92-652

No.

Supreme Court, U.S.
FILED
OCT 14 1992
OFFICE OF THE CLERK

In The

Supreme Court of the United States

October Term, 1992

DAVID E. PAPENDICK, M.D.,

Petitioner,

vs.

LOUIS SULLIVAN, SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN HIS OFFICIAL CAPACITY, APPEALS COUNCIL #000-54-7038,

Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

I. Did the Court of Appeals error when it denied Petitioner review of his due process *Michigan Academy* methodology type issue pertaining to the legality of his Medicare program exclusion, which exclusion was initially determined by a government pre-exclusion decision-maker who was on a quota system which provided for personal financial compensation awards if the decision-maker met his quota and possible discharge if he failed, when the denial of judicial review was on the basis of Petitioner's failure to exhaust administrative remedies when the issue was not subject to administrative review in the first instance and Petitioner's failure consisted of failing to denote the issue in the administrative proceedings which he otherwise exhausted.

II. Did the Court of Appeals error when it affirmed the District Court's refusal to grant limited discovery as to collateral *Michigan Academy* type methodology issues pertaining to the Department's quota system for its pre-exclusion decision-maker when the administrative procedures did not provide for such discovery or review.

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No.

In the

Supreme Court of the United States

October Term, 1992

DAVID E. PAPENDICK, M.D.,

Petitioner,

vs.

LOUIS SULLIVAN, SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN HIS OFFICIAL CAPACITY, APPEALS COUNCIL #000-54-7038,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

PETITION FOR A WRIT OF CERTIORARI

Petitioner, David E. Papendick, M.D., respectfully prays that a writ of certiorari issue to review the judgment and order of the United States Court of Appeals for the Ninth Circuit entered in the above-entitled proceeding on July 17, 1992.

OPINIONS BELOW

On July 17, 1992, the Court of Appeals for the Ninth Circuit issued its opinion and order, reprinted in the appendix hereto, p. 1a, *infra,* denying Petitioner's appeal of the District Court's orders herein. On March 26, 1991, the District Court issued a decision and order, reprinted in the appendix herein, p. 9a, *infra,* granting summary judgment dismissing Petitioner's appeal of United States Department of Health and Human Services administrative determination to exclude Petitioner from being a health care practitioner in the Medicare program. On September 10, 1990, the District Court issued a decision and order granting Respondent a protective order and denying Petitioner discovery herein, reprinted in the appendix herein, p. 24a , *infra.*

The Department's Inspector General issued a notice of exclusion to Petitioner on December 23, 1986, reprinted in the appendix hereto, p. 31a, *infra.* During the administrative review proceedings, the Administrative Law Judge provided in a May 27, 1987, pre-hearing order (¶ F.3.), reprinted in the appendix hereto, p. 38a, *infra,* that "The undersigned has no jurisdiction to rule on constitutional issues. The parties may however insert objections on procedural/constitutional issues in their closing briefs, in order to preserve them for appeal."

STATEMENT OF JURISDICTION

The judgment and opinion of the Court of Appeals was entered on July 17, 1992. The jurisdiction of this Court to review the judgment of the Seventh Circuit is invoked under 28 U.S.C. § 1254(1) and the Fifth Amendment of the United States Constitution.

CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

The Fifth Amendment to the United States Constitution, Due Process Clause.

Statutes:

42 U.S.C. § 405(b); 42 U.S.C. § 405(g); 42 U.S.C. § 1320c-5(b).

Regulations:

42 C.F.R. § 498.82(b); 42 C.F.R. § 1004.60(a); 42 C.F.R. § 1004.90(b); 42 C.F.R. § 1004.90(d); 42 C.F.R. § 1004.100(d); 42 C.F.R. § 1004.100(e); 42 C.F.R. § 1004.120(a); 42 C.F.R. § 1004.120(b); 42 C.F.R. § 1005.21(c); 42 C.F.R. § 1005.21(e).

Federal Register:

Vol. 57, No. 19, Wednesday, January 29, 1992, p. 3325.

STATEMENT OF THE CASE

This case concerns a physician who was excluded from the Medicare programs as a health care practitioner. His exclusion was based upon a Wisconsin Peer Review Organization (WIPRO) recommendation to the Inspector General of the U.S. Department of Health and Human Services to exclude Petitioner for twelve years under provisions of 42 U.S.C. § 1320c-5(b) and the regulations promulgated thereunder. This was based upon his alleged *failure* to comply with his Medicare obligations of standards of care and his alleged *inability* and *unwillingness* to comply with them. Prior to his exclusion, the Petitioner filed civil

suit in the Eastern District of Wisconsin, seeking injunctive relief from alleged due process violations. This suit was dismissed by the District Court for Petitioner's having failed to exhaust his administrative remedies, *Papendick v. Bowen*, 658 F. Supp. 1425 (W.D.Wisc. 1987).

He was excluded by the Inspector General for a period of two years. A notice of exclusion was issued December 23, 1986. Petitioner requested an administrative hearing as to his exclusion. He was afforded a hearing which provided for the review of the substantive issues but the administrative procedures did not afford him an opportunity to litigate constitutional due process methodology issues, as recognized by this Court in *Bowen v. Michigan Academy of Family Physicians*, 106 S. Ct. 2133 (1986). Rather, the Administrative Law Judge (ALJ), assigned the matter, provided in a prehearing order that "The undersigned has no jurisdiction to rule on constitutional issues. The parties may however insert objections on procedural/ constitutional issues in their closing briefs, in order to preserve them for appeal." The administrative procedures did not provide for discovery of such issues. Petitioner's prior counsel did not know of nor insert into the administrative record the issue of the Inspector General's (IG) use of a quota system for and pay awards to his pre-exclusion decision-maker. Petitioner's administrative review was final upon the Appeals Council's June 22, 1989, affirmation of the ALJ's decision, *see* the June 22, 1989, cover letter confirming affirmation reprinted in appendix herein, p. 41a, *infra*. The ALJ's decision had affirmed the OIG's initial determination. Prior to the final affirmation, the Petitioner was reinstated by the IG on February 7, 1989, into the Medicare program, p. 43a, *infra*. This was based upon a determination by the IG that the basis for Petitioner's exclusion no longer existed and that there existed reasonable assurance that the alleged violations of Petitioner would not reoccur, 42 C.F.R. § 1004.120. The Appeals Council's subsequent June 22, 1989, affirmation of Petitioner's exclusion, as well as the

ALJ's determination and the OIG's initial determination, required a finding that the Petitioner was unable and unwilling to comply with his obligations under the Medicare program, 42 U.S.C. § 1320c-5(b).

The IG's quota system provided that the IG's pre-exclusion decision-maker was eligible for financial compensation if the decision-maker excluded a certain number of health care providers from the Medicare program. This quota system is found in the employee Performance Appraisal Plan of the OIG's pre-exclusion decision-maker. If the decision-maker failed to achieve his quota, then he was subject to discharge under his Performance Appraisal Plan. The achievement of the quota was a critical element of the Plan.

Petitioner's current counsel, representing him in his judicial proceedings, filed for discovery in District Court which included a request to produce the decision-maker's Performance Appraisal Plan for the fiscal year covering Petitioner's date of exclusion, December 23, 1986. Also, Petitioner sought, through District Court discovery, the IG's admission of the genuineness of the prior fiscal year's Performance Appraisal Plan for the IG's pre-exclusion decision-maker. This document had been submitted by counsel with the discovery request, pertinent portion reprinted in the appendix hereto, p. 45a, *infra*.

The Department sought a protective order and the District Court granted it. The District Court then entertained and granted a summary judgment motion of the Department to dismiss the Petitioner's complaint for review of his exclusion and constitutional claims. The Seventh Circuit Court of Appeals denied review of the constitutional issue raised herein and other due process issues on the basis that Petitioner failed to exhaust his administrative remedies by failing to raise his due process issues before the Appeals Council. Under HHS rules, the Appeals Council review pertains to review of findings of facts and conclusions of

law previously entered by the ALJ, 42 C.F.R. § 498.82(b) [effective 1/29/92; 42 C.F.R.§ 1005.21(c) and (e)].

The rules in the HHS administrative proceedings did not and do not provide for review of due process issues. Furthermore, Petitioner's administrative proceedings did not provide for discovery procedures.

REASONS FOR GRANTING THE WRIT

It is respectfully submitted that the July 17, 1992, order of the Seventh Circuit Court of Appeals, p. 1a , *infra,* violates the applicable standards of this Court as well as other Courts of Appeal. It is contended that Petitioner herein was denied his rights to litigate constitutional, due process, methodology/procedural type issues which were recognized by this Court in *Bowen v. Michigan Academy of Family Physicians,* 106 S. Ct. 2133 (1986). Furthermore, it is contended that Petitioner was denied his Fifth Amendment procedural due process rights by the Respondent through Respondent's use of a quota system in excluding health-care providers wherein the Respondent provided for potential financial compensation for Respondent's pre-exclusion decision-maker if he obtained his quota of exclusions while the decision-maker faced possible discharge from employment if he failed to obtain his quota of exclusions. This system of financial incentives has been confirmed in *Melashenko v. Bowen*, CV-F-87-533, 1990 WL 159905, at *4-5 (E.D. Cal.). The Court therein enjoined the OIG from "awarding merit pay to a pre-exclusion due process hearing decisionmaker if the merit pay is based upon the outcome of the decision.", pertinent portion reprinted in appendix herein, p. 49a, *infra.*[1]

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1. While modified, the essence of the same pertinent portions of the Performance Appraisal Plan continues to be used today for the OIG's pre-exclusion decision-maker.

While the Wisconsin Peer Review Organization (WIPRO) recommended a twelve year exclusion to the Respondent's Office of Inspector General (OIG), the OIG's pre-exclusion decision-maker reduced Petitioner's exclusion period to two years. The two year period of exclusion was up and he was reinstated in the Medicare program on February 7, 1989, see reinstatement notice, p.43a, *infra*, before his administrative appeal was completed June 22, 1989, *see* notice of final decision, p. 41a, *infra*. For Petitioner to be reinstated in the program, the OIG had to determine that the basis of the exclusion no longer existed and that it had reasonable assurance that there would not reoccur the same violations by Petitioner, which Petitioner allegedly, previously committed, 42 C.F.R. § 1004.120(a). While to exclude the Petitioner from the Medicare program, the Respondent had to determine that Petitioner violated his obligations and was unable and unwilling to comply with his obligations 42 U.S.C. § 1320c-5(b). The same decision-maker made both the exclusion and reinstatement determinations pertaining to Petitioner for the Respondent's OIG. This individual had as a part of his Performance Appraisal Plan the requirement that he exclude a certain number of health-care providers and practitioners in order to be eligible for personal financial compensation. He was subject to discharge if he fails to exclude his numeric quota of practitioners and providers from the Medicare program for this was a critical element in his Performance Appraisal Plan.

The OIG is suppose to insure that the PRO is following appropriate procedures, 42 C.F.R. § 1004.90(b)(1), in the exclusion process, as well as determining that a violation has, in fact, occurred, 42 C.F.R. § 1004.90(b)(2). The PRO's procedures were motivated by its financial considerations as testified to by its witness, Dr. Moulton, at Dr. Papendick's ALJ exclusion hearing.[2]

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2. Dr. Jonathon Moulton, M.D. testified at the Dr. Papendick's ALJ evidentiary hearing on May 28, 1987: "If we don't initiate —if we don't send out a letter of initial termination, we have to pay for all subsequent investigation. If we list — if we send out a

(Cont'd)

However, as seen the OIG's preexclusion decision-maker's own personal monetary considerations precludes an objective review. This is extremely crucial, assuming that a violation occurred, for the PRO is suppose to afford the physician an opportunity to establish his ability and willingness to comply with his obligations by use of a corrective plan, 42 U.S.C. § 1320c-5(b). Similarly, the OIG is suppose to consider the results of that effort in determining if a physician is unable and unwilling to comply with his obligations.

This quota system of the Respondent violates the Court's mandates in *Gibson v. Berryhill*, 411 U.S. 564 (1973) as well as in *Ward v. Village of Monroeville*, 409 U.S. 57 (1972). In *Gibson v. Berryhill*, 411 U.S. 564, 579 (1973), this Court held that "It is sufficiently clear from our cases that those with substantial pecuniary interest in legal proceedings should not adjudicate these disputes." While in *Ward v. Village of Monroeville*, 409 U.S. 57, 61-62 (1972), the Court held that "Petitioner is entitled to a neutral and detached judge in the first instance."

From reading these cases, it is clear that the Respondent's system of imposing exclusion's upon health-care providers is unconstitutionally tainted in the first instance and raises *Michigan Academy, supra*, methodology type of due process procedural issues. These issues being of a constitutional nature were not the subject of the administrative litigation. As this Court held in *Califano v. Sanders*, 430 U.S. 99, 109 (1977): "Constitutional questions obviously are unsuited to resolution in administrative hearing procedures and, therefore, access to the courts is essential to the decision of such questions." Respondent's review procedure

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(Cont'd)

letter of sanction initially, than (sic) the Federal Government starts picking up the costs as part of the sanction proceeding, so that's the way it's done." (Administrative Record, 1820), reprinted in the appendix herein, p. 52a, *infra*.

does not provide for administrative review of constitutional issues. Only substantive issues can be raised in HHS's administrative review process, p. 38a, *infra.* Now, the applicable regulations specifically limit the reviewing administrative law judge from considering the legitimacy of regulations and delegation of authorities 42 C.F.R. § 1005.4(c)(1) (effective 1/29/92). The ALJ in Petitioner's hearing recognized the limitation of HHS review when he offered to permit the Petitioner to document any constitutional objections for subsequent review but specifically denied possession of jurisdiction to consider them himself, p. 38a, *infra.*

The Court of Appeals ruled that Petitioner failed to exhaust his administrative remedies by failing to raise these issues before the Appeals Council, p. 7a, *infra.* However, the Appeals Council had no greater administrative review authority than the ALJ as to constitutional issues, 42 C.F.R. § 498.82(b) [effective 1/29/92; 42 C.F.R. § 1005.21 (c) & (e)]. In the regulatory preamble of the new regulations, the Respondent set out its view as to limitation of administrative review: "Since the ALJ's authority to hear cases comes from the Secretary, the ALJ cannot overrule acts of the Secretary which may have an impact upon these cases." (Fed.Reg. Vol. 57, No. 19, Wed., January 29, 1992, p. 3325). This is and was, obviously, equally applicable to the Appeals Council.

It is Petitioner's contention that as to these *Michigan Academy, supra,* methodology type issues, where the Respondent provides for no administrative review, there is no administrative remedies to exhaust as to these issues. Furthermore, it is Petitioner's contention that if there were remedies to exhaust, then Petitioner was either not required to exhaust them under applicable exhaustion waiver doctrine or that he did exhaust them. Furthermore, as to these type of issues, Petitioner contends that he is entitled to reasonable discovery and creation of a record as incident to any civil litigation with the government.

Administrative and judicial review of the substantive issues of Petitioner's exclusion is pursuant to 42 U.S.C. §§ 405(b) and 405(g). However, the administrative review was and is limited to substantive, non-constitutional issues. There did not and does not exist an administrative procedure to review the constitutional due process issues raised by Petitioner. Thus, judicial review is authorized outside the regulatory structure as held in *Michigan Academy, supra.* If Petitioner is required to exhaust his other administrative remedies as to the substantive issues pertaining to Petitioner's exclusion, then he did do that and his remedies have been exhausted and he is entitled to a review of the collateral methodology issues which he raises herein. If it is correct, as held by the Seventh Circuit, that he should have raised his constitutional issues in his administrative appeal, for the record, prior to raising them judicially, then it must be concluded that waiver is in order. The ALJ did not order that these issues be briefed, but rather, recognizing that they were not subject to administrative review, he permitted them to be noted for the record. The Appeals Council could only consider the issues of fact and conclusions of law determined by the ALJ, 42 C.F.R. § 498.82(b). To only note the issues serves no functional purpose in the administrative process and futility is one of the grounds which justify waiver of exhaustion of administrative remedies, *Ellison v. Califano*, 546 F.2d 1162, 1164-1165 (5th Cir., 1977). Furthermore, as the Ninth Circuit has held in *Girard v. Klopfenstein; Conservation Service an Agency of the U.S. Department of Agriculture*, 930 F. 2d 738, 740-741 (1991) constitutional issues need not be exhausted administratively for they are collateral to the substantive claim before the agency. This Court, itself, held that exhaustion of administrative remedies may be waived in *Mathews v. Eldridge*, 424 U.S. 319, 330 (1976), when "the constitutional claim is entirely collateral to [the] substantive claim"; *also see, Bowen v. City of New York*, 476 U.S. 467, 484 (1986).

As to Petitioner's being permitted reasonable discovery,

without an administrative record, the Court ought to permit the creation of a record as to the constitutional issues so that a basis for a determination may exist. A court cannot review a nonexistent record, *Jorman v. Veterans Administration*, 579 F. Supp. 1407, 1416 (N.D. Ill.1984). These methodology issues are no different than any other claims against the United States concerning which the Court has permitted discovery, *United States v. Procter & Gamble Co.*, 356 U.S. 677, 681 (1958). If the Court is to permit judicial review of administrative methodology issues as it held in *Michigan Academy, supra*, then it should within reasonable limits, regulated by the sound discretion of the District Court, permit this type of discovery. It happens that a party may perceive that he is being denied due process and without discovery, he would be denied the ability to articulate and define his deprivation in the format of a reviewable record. Petitioner filed a prior, initial suit when he was first being excluded, asserting that his due process rights were being denied as to certain other issues, *Papendick v. Bowen*, 658 F. Supp. 1425 (W.D. Wisc. 1987). However, his prior counsel, without the availability of discovery, was unaware of the OIG's quota system. Thus, he was without the information necessary to note in the administrative record the issue raised herein. The OIG was and is suppose to insure PRO regulatory compliance, 42 C.F.R. § 1004.90(b). However, the OIG's quota system negates the effectiveness of this function.

To what degree a party would be entitled to either pre- or post-administrative judicial review and discovery for methodology type constitutional issues would be addressed on a case by case basis by the District Court so as to insure that administrative procedures are not unduly delayed nor crucial constitutional rights denied. However, the issue of discovery and potential interference with

governmental process is routinely addressed when parties sue the government or its agents in a non-administrative context. Here in any event, Petitioner is clearly entitled to judicial discovery and review due to the concrete demonstrable nature of the government's violative conduct.

CONCLUSION

Because the Petitioner suffered constitutional deprivation and has no administrative remedy, the Court should provide such. It is no consolation that certain substantive administrative review is available when his rights have been violated in a procedural manner. Proper procedures facilitate proper substantive determinations. Complex medical reviews were and are tainted by the OIG's biased decision-maker. As the Court has already noted in *Village of Monroeville, supra,* 61-62, Petitioner "is entitled to a neutral and detached judge in the first instance." This is even more important in a case such as this, compared to the circumstance of *Village of Monroeville, supra.* In *Village of Monroeville, supra,* only a traffic offense was involved, with relatively minor consequences and a minimal complexity of facts and issues to be considered.

In the present case, complex factual circumstances as well as significant legal issues are involved and must be resolved. This necessitates that the OIG's pre-exclusion decision-maker is objective and without bias. The OIG's pre-exclusion decision-maker has the ability and responsibility to review and evaluate the information submitted by the PRO and practitioner 42 C.F.R. § 1004.60(a) to determine if a violation has occurred, whether or not a practitioner is able and willing to comply with his obligations and if a sanction is warranted, 42 C.F.R. §§ 1004.90(b) and .90(d). Furthermore, the OIG's pre-exclusion decision-maker will determine an appropriate sanction; *i.e.,* whether to impose a monetary penalty or an exclusion and if an exclusion, for what

period of time, 42 C.F.R. § 1004.90(d). There is a significant difference in consequencesfor a practitioner based upon whether the OIG pre-exclusion decision-maker imposes an exclusion or monetary penalty. The preexclusion decision-maker has that discretion and his discretion has been tainted by the quota system imposed upon him.

These exclusions involve substantial issues which result in a significant professional stigma, if an exclusion is imposed, because of the OIG's subsequent reporting requirements, 42 C.F.R. §§ 1004.100(d) and .100(e). The practitioner's exclusion is reported to licensing authorities as well as hospitals and other professional organizations. Furthermore, the OIG's exclusion will remain in effect until the OIG's determination to exclude is reversed by a hearing decision, 42 C.F.R. §§ 1004.120(b). Thus, it is extremely important that a fair and impartial initial adjudication occur in the first instance. Without such a fair and impartial initial adjudicator, a practitioner is prejudiced in the first instance and he may never be afforded an adequate means of correcting that initial loss.

Respectfully submitted,

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Dated: October 13, 1992

APPENDIX A — JULY 17, 1992, SEVENTH CIRCUIT COURT OF APPEALS DECISION AND ORDER AFFIRMING DISTRICT COURT DECISION

In the

United States Court of Appeals

For the Seventh Circuit

No. 91-1902

DAVID E. PAPENDICK, M.D.,

Plaintiff-Appellant,

v.

LOUIS W. SULLIVAN, Secretary of the United States Department of Health and Human Services, in his official capacity,

Defendant-Appellee.

Appeal from the United States District Court
for the Eastern District of Wisconsin.
No. 89 C 1005—**Robert W. Warren,** *Senior District Judge.*

ARGUED JANUARY 14, 1992—DECIDED JULY 17, 1992

Before BAUER, *Chief Judge*, COFFEY, and EASTERBROOK, *Circuit Judges.*

BAUER, *Chief Judge.* In May 1986, the Wisconsin Peer Review Organization (WIPRO)[1] notified David E. Papen-

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[1] WIPRO is a peer review organization authorized to review the professional activities of physicians and other health care practitioners who render services under the Medicare program. *See* 42 U.S.C. § 1320c-3(a)(1). As its name implies, a peer review organization is composed of, or has available to it, a substantial number of licensed medical doctors or osteopaths who are representative of the practicing physicians in the area. 42 U.S.C. § 1320c-1(1)(A).

dick that after routine review procedures, it determined that he grossly and flagrantly violated the statutory obligations imposed on physicians who provide medical services under Medicare. WIPRO informed Papendick that he had thirty days within which to submit additional information that would modify its position, or he could request a meeting with WIPRO to review and discuss specific cases. This action triggered an administrative review process, of which Papendick has taken full advantage. We are the fifth adjudicative body to consider the issues WIPRO raised.

Papendick responded by sending a letter to WIPRO asking that it review documents he submitted to a review organization several years earlier that dealt with other cases. Regarding the specific cases WIPRO raised, Papendick responded that WIPRO's accusations were a gross misrepresentation of the medical care he provided, but he declined the opportunity to meet with WIPRO. Thereafter WIPRO notified Papendick that it had recommended to the Department of Health and Human Services (HHS) that he be excluded from the Medicare program for a period of twelve years, and that he had thirty days to submit additional information to HHS.

Papendick then submitted a letter to HHS's Office of the Inspector General (OIG), setting forth his reasons why he should not be excluded from the Medicare program. On December 23, 1986, after a full review of all the material before it, OIG found that Papendick grossly and flagrantly violated his statutory obligation to provide medical care that meets professionally recognized standards in his treatment of two patients, designated in the record as H.D. and L.M. The OIG advised Papendick that it was excluding him from the Medicare program for two years. As a result of that action, Papendick requested an administrative hearing.

The matter was heard before an Administrative Law Judge (ALJ) on February 16, 1987. The parties stipulated to the issues: whether Papendick grossly and flagrantly

violated provisions of section 1156 of the Social Security Act, 42 U.S.C § 1320c-5(a),[2] and if so, what sanction would be appropriate. In resolving these issues, the ALJ would be required to determine the appropriate standard of professional care, and whether Papendick was willing and able to comply substantially with his section 1156 obligations. The ALJ advised the parties that if they had either procedural or constitutional objections, they could raise them in their closing briefs in order to preserve them for appeal. On December 28, 1987, employing a statewide standard of care, the ALJ found that Papendick grossly and flagrantly violated professionally recognized medical standards in the care of both H.D. and L.M. He also found that Papendick demonstrated both an unwillingness and an inability to comply with his statutory obligations. Consequently, he upheld Papendick's two-year exclusion from the Medicare program.

Dissatisfied with that result, Papendick filed a request for review to the Social Security Administration's Appeals Council. In the meantime, on February 7, 1989, he was reinstated to the Medicare program.[3] At the expiration of

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[2] The section requires, in pertinent part, that a health care practitioner who provides services under the Medicare program shall assure that those services

> (1) will be provided economically and only when, and to the extent, medically necessary;
>
> (2) will be of a quality which meets professionally recognized standards of health care; and
>
> (3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

42 U.S.C. § 1320c-5(a).

[3] Even though he is no longer excluded from the Medicare program, Papendick continues to press his appeal, claiming that exclusion has damaged his reputation and that if he is successful, he is entitled to retroactive reimbursement under the Act.

his two-year exclusion, the Inspector General determined that there was reasonable assurance that the problems that led to Papendick's exclusion would not reoccur and reinstated him. Nonetheless, on June 22, 1989, after reviewing the entire record, the Appeals Council affirmed the ALJ.

So Papendick took the matter to the United States District Court, as provided in 42 U.S.C. § 405(g). On August 18, 1989, he filed a complaint against defendant Sullivan ("the Secretary") seeking review of his exclusion from the Medicare program. Additionally, he alleged the existence of certain collateral issues not cognizable in the administrative process. He then made discovery requests of the Secretary under FED. R. CIV. P. 36 for admissions, and under FED. R. CIV. P. 34 for the production of documents. In response, the Secretary moved for a protective order. After reviewing the parties memoranda, the district court granted the Secretary a protective order on September 10, 1990. The parties then filed cross-motions, Papendick for a reversal or a remand, the Secretary for summary judgment. After both motions were fully briefed, the district court denied Papendick's motion and granted summary judgment in the Secretary's favor.

Papendick filed this appeal on April 19, 1991. Although his brief is not a model of clarity, we believe we understand his various arguments to: challenge the record evidence supporting the ALJ's decision, assert that the ALJ applied an incorrect standard of professional care, claim that the district court abused its discretion when it granted the Secretary's motion for a protective order, and claim that he was denied due process. He also argues that the case should be remanded to consider new evidence. Because none of these arguments are meritorious, we affirm the district court.

Papendick's initial argument invites us to reconsider and reweigh the evidence before the ALJ. Because that is not the function of appellate review, we decline. We are to determine only if there is substantial evidence in the rec-

ord to support the ALJ's decision. *See* 42 U.S.C. § 405(g). "Substantial evidence may be less than a preponderance of the evidence." *Freeman United Coal Mining Co. v. Stone*, 957 F.2d 360, 362 (7th Cir. 1992). Further, "[t]he existence of an evidentiary dispute, in and of itself, does not present a ground for reversing the ALJ's decision to credit one particular version of the events over another." *Herr v. Sullivan*, 912 F.2d 178, 181 n.4 (7th Cir. 1990).

We are convinced that there is not only substantial, but abundant evidence in the record to support the ALJ's decision that Papendick grossly and flagrantly violated his section 1156 obligations. First, the record as a whole supports the finding that Papendick failed to provide H.D. with the care required under section 1156 by failing to recognize the severity and deteriorating quality of his cardiac condition, failing to administer tests that would have disclosed his deteriorating condition, and failing to obtain an outside independent consultation, all of which placed H.D. at greatly increased risk of harm. As to L.M., the record shows that Papendick again failed to obtain an independent expert cardiac consultation about her condition, and in fact, considered her terminal, making a "no code" notation on her chart even though neither she nor her family consented to the notation, all of which also placed her in imminent danger and greatly increased risk of death.[4]

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[4] In a related argument, Papendick claims the ALJ's consideration of the "no code" notation on L.M.'s chart went beyond the stipulated issues, violating his due process right to be notified of the charges against him. This argument is specious because it completely ignores the ALJ's observation that

> the "no code" factor had not been specifically charged against the Petitioner by WIPRO or OIG, but that factor nevertheless must be considered as part of the Petitioner's failure to obtain a consultation, illustrative of his state of mind in failing to secure additional cardiological workups (echocardiograms and catheterizations), and further *goes to the issue of gross and flagrant*. The expert witnesses called to testify, Drs. Moulton and Fergus, both concurred that based on the lack of consulta-

(Footnote continued on following page)

Appendix A

The ALJ's determination that Papendick was unwilling and unable to comply substantially with his section 1156 obligations similarly is supported by substantial evidence. The record clearly discloses that Papendick, in his testimony before the ALJ, failed to recognize or appreciate that the quality of treatment he rendered to H.D. and L.M. placed them at greatly increased risk of death or further harm. Indeed, he testified that he would have done nothing differently, and that the only reason he would seek outside expert consultation now was because the hospital at which he practiced no longer functioned as a full service hospital. This evidence easily supports the ALJ's decision and, consequently, Papendick's two-year exclusion from the Medicare program.

Papendick further argues that the ALJ applied an incorrect standard of professional care when he concluded that he violated his section 1156 obligations. The ALJ employed a statewide standard, which was the standard WIPRO used as well. The regulations promulgated for peer review under the Social Security Act require WIPRO to "determine whether the quality of the services meets professionally recognized standards of health care." 42 C.F.R. § 466.71(a)(2). The regulatory preamble to those regulations states, in pertinent part, that

> In rendering medical judgments, the [peer review organizations] must apply, as principal points of evaluation and review, professionally developed norms of care, diagnosis and treatment based on typical patterns or practice *within the geographic area served by the organization.*

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[4] *continued*
tion with the patient and her family *a significant gross and flagrant violation had occurred with the first "no code" entry.*
Decision of the ALJ, Administrative Record at 946 (emphasis ours). It is clear that the ALJ considered the "no code" entry not as a separate charge against Papendick, but as it related to whether he grossly and flagrantly violated his section 1156 obligations in his care of L.M. This was entirely proper.

50 Fed. Reg. 15337 (Apr. 17, 1985) (emphasis ours). As the ALJ noted, the State of Wisconsin is the geographic area WIPRO serves. The ALJ, therefore, did not err in applying a statewide standard of professional care.

Next, Papendick argues that the district court abused its discretion when it granted the Secretary's motion for a protective order after Papendick served the Secretary with discovery requests. Trial courts are vested with broad discretion in ruling on discovery issues, and will be reversed only on a clear showing that the party seeking discovery will suffer actual and substantial prejudice if discovery is denied. *Travelers Ins. Co. v. Transport Ins. Co.*, 846 F.2d 1048, 1053 (7th Cir. 1988).

Papendick fails to show how entry of the protective order, which limited the district court's review strictly to the administrative record before it, actually and substantially prejudiced him. The district court's jurisdiction to review Papendick's exclusion from the Medicare program was pursuant to 42 U.S.C. § 405(g), which is limited to a review of the pleadings and the transcript of the administrative record. *See* 42 U.S.C. § 405(g). It is clear from the statute that a district court may not consider evidence outside the certified record. But that is what Papendick's discovery requests sought. The court, therefore, did not abuse its discretion.

Papendick also argues that his due process rights were violated because of defects he claims occurred at the administrative hearing and because of WIPRO's alleged conflicts of interest. The ALJ recognized that he had no jurisdiction to review constitutional claims, and so notified both parties: "the parties may . . . insert objections on procedural/constitutional issues in their closing briefs, in order to preserve them for appeal." Administrative Record at 1281. Nevertheless, Papendick did not raise his due process claims in his appeal to the Appeals Council. Our rule is that these issues must first be raised administratively. *Weyerhaeuser Co. v. Marshall*, 592 F.2d 373, 376 (7th Cir. 1979). As did the district court, we decline to consider issues not considered by the Appeals Council.

Finally, Papendick argues that we should remand to the district court, with instructions to remand to the ALJ, to consider new evidence. The new evidence Papendick wishes to offer is the Inspector General's notification that, after having determined that the basis for Papendick's two-year exclusion no longer existed, and having received reasonable assurance that the problems would not reoccur, Papendick was reinstated to the Medicare program.

A remand under 42 U.S.C. § 405(g) for consideration of new evidence is appropriate only when the new evidence is material to the "condition during the relevant time period encompassed by the [exclusion] under review, and there is good cause for not introducing the evidence during the administrative proceedings." *Anderson v. Bowen*, 868 F.2d 921, 927 (7th Cir. 1989). The relevant time period here is the period of time Papendick treated H.D. and L.M. At the conclusion of his review of his treatment of those two patients, the ALJ determined that Papendick was unwilling and unable to comply substantially with his section 1156 obligations. The Inspector General determined, on review of Papendick's reinstatement petition, that he was now reasonably assured that Papendick would comply with his statutory obligations. Papendick's assurances, and the Inspector General's determination, both post-date the relevant time period and are, therefore, not material.

For the foregoing reasons, the decision of the district court is

AFFIRMED.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Seventh Circuit

APPENDIX B — MARCH 26, 1991, DECISION AND ORDER OF DISTRICT COURT GRANTING DEFENDANT SUMMARY JUDGMENT

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Case No. 89-C-1005

DAVID E. PAPENDICK, M.D.,

Plaintiff,

v.

LOUIS W. SULLIVAN, Secretary of the Department of Health and Human Services,

Defendant.

DECISION AND ORDER

The defendant's summary judgment motion and the plaintiff's motion "to reverse the defendant Secretary's exclusion of plaintiff or in the alternative to remand this matter for further proceedings in accordance with the opinion of the Court" are before the Court.[1]

I. FACTUAL AND PROCEDURAL BACKGROUND

The Court set out this action's factual and procedural background at pages 1-2 of its September 10, 1990 *Decision and Order* granting the defendant's motion for a protective order pursuant to Fed.R.Civ.P. 26(c). Further recitation of relevant facts occurs *infra* at part III.

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1. Both parties have moved to file briefs in excess of the page limit requirements of Local Rule 6.01. Because both motions appear to be well-founded, the Court GRANTS them.

Appendix B

II. STANDARD OF REVIEW

Title 42 U.S.C. § 405(g) permits a district court to enter judgment upon the pleadings and transcript of the record and provides that the findings of the Secretary as to any fact, if supported by substantial evidence, are conclusive. The Secretary's decision must be upheld if the determination is "supported by 'substantial evidence on the record as a whole.' " *Walker v. Bowen*, 834 F.2d 635, 639 (7th Cir. 1987). "The existence of an evidentiary dispute, in and of itself, does not present a ground for reversing the ALJ's decision to credit one particular version of the events over another." *Herr v. Sullivan*, 912 F.2d 178, 181 n.4 (7th Cir. 1990). A district court is not to decide facts anew, reweigh evidence, or substitute its judgment for that of the Secretary. *Delgado v. Bowen*, 782 F.2d 79, 82 (7th Cir. 1986).

III. DISCUSSION

A. Defendant's Summary Judgment Motion

Peer review organizations ("PRO") provide quality control to insure that participating physicians comply with Social Security Act obligations to provide economical, necessary, and quality medical services. 42 U.S.C. § 1320c-9. The PRO for a particular area reviews physicians' professional activities relating to their provision to Medicare beneficiaries. 42 U.S.C. § 1320c-3(a)(1); 42 C.F.R. § 1004.30. If a PRO identifies a violation of an obligation, it must determine the nature of that violation. 42 C.F.R. § 1004.40. If the PRO determines that the violation is gross and flagrant, it must give the physician written notice setting out this determination, its basis, and the sanction that will be recommended. 42 C.F.R. § 1004.50. After reviewing the information provided by the physician in writing or at a meeting in response to this determination, the PRO considers whether the physician violated

the Social Security Act obligations. *Id.* If the PRO determines that there has been a gross and flagrant violation, the PRO must submit a report and recommendation to the Office of Inspector General ("OIG"). 42 C.F.R. § 1004.60. If the Secretary agrees with the PRO determination, the Secretary may exclude the practitioner from the Medicare program. 42 U.S.C. § 1320c-5(b)(1). An excluded individual is entitled to reasonable notice and an opportunity for hearing as provided in 42 U.S.C. § 405(b), and to judicial review of the Secretary's final decision pursuant to 42 U.S.C. § 405(g). 42 U.S.C. § 1320c-5(b)(4). An excluded physician is entltled to an evidentiary hearing before an Administrative Law Judge. 42 U.S.C. § 1004.130(a)(1); 42 C.F.R. §§ 405.1530-.1595. The physician can call witnesses, cross-examine them, submit documents and briefs, and present argument. 42 C.F.R. § 405.1547-.1548. The hearing is transcribed, and witnesses may be subpoenaed. 42 C.F.R. § 405.1544,-.1599. The ALJ's decision is appealable to the Appeals Council, which renders the final agency action. The Appeals Council decision may be appealed to the district court. 42 C.F.R. § 405.1561,-.1567; 42 U.S.C § 1320c-5(b)(4); § 405(g).

On May 22, 1986, the Wisconsin Peer Review Organization ("WIPRO") informed the plaintiff that it had initially determined that he had grossly and flagrantly violated his Social Security Act obligations. A.R. 2338-42. WIPRO notified the plaintiff that it intended to recommend that the Secretary exclude the plaintiff for 12 years. The plaintiff submitted a letter asking that WIPRO review documents and tape recordings. A.R. 2392. After review of these submissions, WIPRO recommended that the plaintiff be excluded from the Medicare program for 12 years. *Id.* The plaintiff's attorney wrote to the OIG asking him to reject WIPRO's recommendation to exclude the plaintiff. A.R. 2416-40. The OIG excluded the plaintiff from the Medicare program for 2 years. A.R. 2441-44. On February 16, 1987, the plaintiff requested an administrative hearing. A.R. 2445-46. An ALJ conducted the hearing on May 28-29 and June 1-2,

1987 in Green Bay, Wisconsin. A.R. 1624-2336. On December 28, 1987, the ALJ found that the two-year exclusion was appropriate because:

(1) the plaintiff's failure to use adequate diagnostic skills led to his failure to recognize the deteriorating condition of a patient, placing the patient at unnecessary risk, which grossly and flagrantly violated his obligation to provide health care meeting professionally recognized standards; also, his failure to obtain timely outside cardiac consultation in light of the patient's rapidly deteriorating condition constituted a gross and flagrant violation of professionally recognized medical standards;

(2) the plaintiff's failure to obtain a timely expert cardiac consultation and classification of another patient as "terminal" and designation of a "no code" in the physician's orders without specific consultation with the patient and/or family members grossly and fragrantly violated the plaintiff's obligation to provide health care meeting professionally recognized standards; and

(3) from his testimony and actions, the plaintiff has not demonstrated a willingness or lack of ability to comply with the Social Security Act obligations. A.R. 911-955.

On February 24, 1988, the plaintiff filed a request for review of the ALJ's decision. A.R. 2886-89. The plaintiff and the OIG filed submissions with the Appeals Council. A.R. 2890-2978; 2982-3062. The Appeals Council granted the plaintiff's request for review, A.R. 909-10, and on June 22, 1989 affirmed the ALJ's decision, including the two-year exclusion. A.R. 5-11.

The voluminous record before the Court includes the testimony at four days of hearings before the ALJ, the written

submissions by the plaintiff to WIPRO and the OIG before the plaintiff's exclusion, the medical records of the patients at issue, and the evidence the plaintiff submitted to the Appeals Council. The lens through which this Court views the record is particular: the Court must determine whether the Secretary's decision is supported by substantial evidence. Substantial evidence means more that a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. If the Secretary's decision is supported by substantial evidence, this Court affirms the Appeals Council's decision, unless the plaintiff has raised a legal error. *Herr v. Sullivan*, 912 F.2d 178, 180 (7th Cir. 1990) (quoting *Steward v. Bowen*, 858 F.2d 1295, 1297 (7th Cir. 1988)).

1. Patient 1 – H.D.

H.D. was a sixty-five year-old male admitted to the Algoma Memorial Hospital emergency room on October 5, 1985. He arrived in acute distress and agitation after developing substernal chest pain and shortness of breath. A.R. 2761. He had experienced chest pain for one month prior to admission. A.R. 2764. The admitting diagnosis was acute myocardial infarction. *Id.* Enzyme level tests and EKG findings corroborated the conclusion of a heart attack. H.D. also displayed congestive heart failure and lowered kidney function. These signs indicated deterioration, and continued over the four and fifth days after admission, October 8-9, 1985. On October 9th H.D. had low blood pressure and pulse readings. That evening, the plaintiff went on a trip and H.D. came under the care of Dr. Weisse. H.D. experienced respiratory and cardiac arrests that night. He was revived and transferred to Green Bay Bellin Hospital. He died three days later of irreversible cardiogenic shock. A.R. 927.

The plaintiff testified at the hearing before the ALJ that in his opinion H.D. had stabilized by 1 a.m. on Sunday, October 6th and

was stable through October 8th. Yet Dr. Moulton, OIG's witness, and Dr. Fergus, the plaintiff's witness, testified that after reviewing the enzyme tests, chest x-rays, electrocardiographs, and the clinical findings as reflected in the nurse's notes and physician's orders, H.D.'s condition had deteriorated significantly on October 7-8. *See* Defendant's Memorandum pp. 13-14; pp 14-15. Opinion testimony from Dr. Moulton that an October 6th EKG was abnormal, A.R. 2777, that "an accelerating surge of destabilization beg[an] about the second hospital day," A.R. 1696, that H.D. could have benefitted from a consultation, which could have improved his survival chances, A.R. 1708, and that the plaintiff's treatment of H.D. failed to meet professionally recognized standards in that he failed to recognize the significant deterioration and failed to get adequate consultation to see that the patient was evaluated by a cardiologist, *id.*, supports the Secretary's decision. Further, testimony from Dr. Fergus, plaintiff's witness and a board certified cardiologist, that H.D.'s condition was deteriorating, A.R. 2091, that from admission until October 8th there was increasing damage to the heart and that H.D. experienced chest pains, *id.*, that because the patient had chest pain on October 7th and became restless evidenced an injury to the heart muscle, A.R. 2111, and that prior to H.D.'s condition worsening the patient could have been transferred to a cardiac consultant, A.R. 2096-97, also supports the Secretary's decision.

This testimony is properly characterized as substantial evidence which supports the Secretary's decision that the plaintiff grossly and flagrantly violated his obligations with regard to patient H.D. This record evidence could be accepted as adequate to lead a reasonable mind to the conclusions that the plaintiff failed to employ adequate diagnostic skills, thereby failing to recognize H.D.'s deteriorating condition, and that the plaintiff failed to obtain timely outside cardiac consultation in light of H.D's rapidly deteriorating condition. The ALJ could properly find from Dr.

Appendix B

Moulton's testimony and the WIPRO panel findings that it was a professionally recognized statewide standard of care to seek outside consultation in complicated heart cases, A.R. 938, and that the plaintiff failed to do so. The defendant has therefore proffered sufficient evidence to support the Secretary's conclusions as to patient H.D. The plaintiff's claims to the contrary rely on inferences and testimony favorable to his position that the ALJ considered, and resolved against him. This Court is to defer to the ALJ's resolution of the factual dispute in a case in such a posture.

2. Patient 2 – L.M.

L.M. was a sixty-five year-old woman admitted to Algoma Memorial Hospital for a number of lengthy stays from November 1984 through March 1985. She was experiencing chest pain, shortness of breath, and her conditions included congestive heart failure and arteriosclerotic heart disease with angina and arrhythmias. After her fourth stay, a physician other than the plaintiff readmitted her on March 10, 1985, and transferred her to Green Bay Bellin Hospital four days later. A.R. 1307. After the transfer, L.M. was considered for referral for electrophysiologic studies for her intractible arrhythmias; before that she underwent cardiac catheterization and coronary arteriography which showed her at high risk for cardiac mortality. Part of her primary treatment included coronary bypass surgery. L.M. survived the surgery and her health improved. A.R. 2430-31; 2435-36; 2471-72. L.M.'s primary treating physician during her four previous hospital stays was the plaintiff, who had control over the care and services rendered to her. A.R. 953.

The plaintiff's treatment of L.M. during the four hospitalizations before her final transfer to Bellin Hospital are at issue. In the first, November 9, 1984, the admitting diagnosis was

acute chest pain and shortness of breath. A.R. 2497, 2519. The plaintiff treated L.M. for chest pain, and discharged her on November 13, 1984 with complete relief of the chest pain. A.R. 2533. In the second, November 29, 1984, L.M. was readmitted to the emergency room by Dr. Weisse, again complaining of chest pain and shortness of breath. A.R. 2537. During this admission the patient experienced acute cardiac arrythmias, which were treated with medication but persisted upon discharge. A.R. 2539. On November 29, 1984 at 6:10 p.m. the plaintiff wrote a "no code" order for L.M., noting on the progress record "Progressive demise past few months [–] no heroics." A.R. 2583. A consult report was done by Dr. March on December 2, 1984. A.R. 2581. Upon discharge from this admission on December 14, 1984, L.M. was diagnosed to have acute cardiac arrhythmias with secondary acute and chronic congestive heart failure, and acute angina. A.R. 2624. The plaintiff noted that the cardiac arrhythmias persisted but that L.M.'s general condition appears to be stabilized. *Id.*

In the third admission on February 1, 1985, L.M. was readmitted and diagnosed to have congestive heart failure. A.R. 2626. L.M. complained of shortness of breath and fatigue and had poor response to outpatient treatment for congestive heart failure. A.R. 2629. She again experienced severe tachyarrythmias with extensive premature ventricular contractions. A.R. 2677. The patient continued to be treated with various medications and was discharged on February 14, 1985. In her fourth admission on February 19, 1985, L.M. was again admitted under the plaintiff's care. She complained of shortness of breath and chest pain. A.R. 2675. The admitting diagnosis was acute myocardial infarction. A.R. 2729. The plaintiff noted the patient's intolerance to certain medications and described her as having "a rather morbid outlook for future salvageability." A.R. 2675. On February 21st the plaintiff entered a no code order. Upon discharge on March 1st, the plaintiff noted that L.M. had been admitted with ventricular instability

which he described as "with known problems with the past 2 previous admissions at least." He told the family that he did not expect her to survive. A.R. 2756.

Dr. Moulton testified regarding L.M.'s second admission that plaintiff had entered a no code on the day of admission, A.R. 1844, which means that if "a cardiac or respiratory arrest occurs that efforts should not be made to resuscitate the patient." A.R. 1841. Dr. Moulton testified that the fact that a patient is near death is not reason alone to enter a no code. A.R. 1841-42. He stated that the appropriate procedure for no code orders is to discuss them with the patient, if competent, get the patient's acquiescence, and discuss it with the family as well. *Id.* The d scussions with the patient and the family should be documented in the progress notes. *Id.* Dr. Moulton testified that nothing in the progress notes indicated that the plaintiff had discussed the subject of a no code order with the family. *Id.* L.M. had stated upon admission that "if she didn't get better she wanted to go someplace else." Dr. Moulton testified regarding that statement that it did not appear to him that L.M. considered herself terminal, but that if progress was not made, that she would like somebody else to look at her problems. A.R. 1848. In Dr. Moulton's opinion L.M.'s problems after the second discharge were "accelerating." A.R. 1851-53. He opined that nothing had been done through the two admissions to affect the patient's underlying problems. A.R. 1853. Dr. Moulton testified that "one would consider cardiac consultation to see if there is any surgical alternative, any further medication alternatives, because she has had a lot of the standard treatment and is continuing to do poorly." A.R. 1854.

Dr. Moulton testified that in his opinion, during L.M.'s third hospitalization, she gradually deteriorated and began having more arrhythmias. A.R. 1858. For the fourth admission, Dr. Moulton noted that the plaintiff again entered a no code order without a

notation of consultation with the patient or her family. A.R. 1859. Dr. Moulton noted that on February 21, 1985 at 2 p.m., L.M.'s son was at the hospital and talked with the nurses about having a specialist see L.M. A.R. 1860. Dr. Moulton concluded that this request regarding the specialist contradicted the plaintiff's no code order. A.R. 1860-61. Opining on L.M.'s condition between the first and fourth admissions, Dr. Moulton stated: "The therapeutic regimen available to her in Algoma had been pretty much exhausted without any basic correction of underlying problems and no expert consultation in what I feel is a very difficult case." A.R. 1863-64 .

Dr. Moulton concluded that the underlying causes of L.M.'s symptoms were not adequately addressed. A.R. 1864 . He concluded that the plaintiff did not obtain appropriate and timely consultations because he determined the plaintiff was terminal and nothing could be done. Dr. Moulton was of the opinion that a consultation could have determined treatment alternatives such as a change of medications, an evaluation of the conduction system, A.R. 1935, or surgery. A.R. 1854. Dr. Moulton concluded that the plaintiff's failure to obtain a consultation was a gross and flagrant violation of the Social Security Act obligations. A.R. 1885-86. He stated that the no code issue was a large part of the failure to get adequate consultation. A.R. 1980. He also testified that an echocardiogram and a cardiac catheterization should have been done. A.R. 1981. He concluded that L.M. was classified a no code without adequate information, A.R. 1891, and that the plaintiff placed the patient in imminent danger or in unnecessarily high risk. *Id.*

Dr. Fergus, plaintiff's witness and a Green Bay cardiologist, testified that because the plaintiff had had an outside consultation for L.M. in 1983, no need for another existed because L.M. was a poor candidate for surgery. A.R. 2127. But he also testified that

"where it is obvious at that point that medical management is going nowhere, and, therefore, maybe it's time for another review of the situation based on those facts, because that's a lot different from where she was two years earlier." A.R. 2128. Dr. Fergus then acknowledged that by the end of the patient's third admission, her medical management was going nowhere. A.R. 2145. He stated that at that point "the question could have arisen as to whether or not the desperate situation had risen where you might think that an operation of a significantly higher risk than average might be justified." A.R. 2148. Dr. Fergus did not agree that L.M. was terminally ill. A.R. 2138. Dr. Fergus agreed with Dr. Moulton that the statement of L.M. on November 30, 1984 that "if she did not get better she wanted to go someplace else" did not reflect a person who does not want treatment if a crisis arises. A.R. 2159. Dr. Fergus stated that L.M. was placed at increased risk by the no code order of November 29, 1984, and by the orders disconnecting telemetry and taking the patient off Lidocaine. A.R. 2160, 2163. Dr. Fergus stated that those orders, if done without family consultation, would violate accepted medical standards. A.R. 2164.

The record evidence is adequate to lead to the reasonable conclusions that the plaintiff did nothing during the first two admissions to affect L.M.'s underlying problems, that a consultation could have determined a number of treatment alternatives, such as a change of medications, an evaluation of the conduction system, and the possibility of surgery, and that L.M.'s medical condition did not justify the no code and that neither L.M. nor her family consented to it. *See* A.R. 948. The record testimony is properly characterized as substantial evidence which supports the Secretary's decision that the plaintiff grossly and flagrantly violated his obligations with regard to patient L.M. The ALJ could properly find from Dr. Moulton's testimony that the plaintiff's failure to seek a cardiac consultation when it became apparent that the course of treatment was ineffective and her condition

deteriorated, as well as from Dr. Fergus's testimony that the patient's situation had changed and therefore that the plaintiff could not have relied on the two-year old consultation, that the plaintiff's actions placed L.M. at substantial risk and in very real danger of imminent death. A.R. 948.

The defendant has proffered sufficient evidence to support the Secretary's conclusions as to patient L.M. Again, the plaintiff's claims to the contrary rely on inferences and testimony favorable to his position that the ALJ considered, and resolved against him. This Court is to defer to the ALJ's resolution of the factual dispute in a case in such a posture. The Secretary reasonably concluded, based upon the record before the Court, that the plaintiff failed to obtain outside consultation, placing L.M. at unnecessary risk. Drs. Moulton and Fergus testified that designating L.M. as no code, if done without the patient's and family's consent, violated professionally recognized standards and placed the patient at unnecessary risk. The evidence fails to bear out adequate justification for the no code in this case.

3. Plaintiff Unwilling and Unable to Comply with Social Security Act Obligations

The statute requires that a gross and flagrant violation of a physician's § 1156 obligations in addition to an unwillingness and/or inability to comply with these obligations can result in expulsion. The ALJ found that the plaintiff's unwillingness was reflected in his decision to forego his opportunity to meet with the PRO and discuss the matters leading to its sanction recommendation. A.R. 949. Dr. Moulton supported this conclusion when he testified that the plaintiff's decision not to use the opportunity to meet with the peer review committee before it recommended indicated this unwillingness. A.R. 1712, 1714-15. Because that opportunity could have allowed for an identification of the plaintiff's continuing

medical education ("CME") needs relevant to the deficiencies cited by WIPRO, and provision of that CME under arrangements that assured WIPRO that the CME was appropriate and effective. A.R. 1712-13.

The plaintiff's answer to this point was that he did not meet with the peer review board because he did not think he would get a "fair shake" based on his past experience. A.R. 1988-90. Judge Shabaz found this excuse lacking. A.R. 1877-78. *See also* A.R. 2847-88, 2857-58, 2861-62. Further, after receiving WIPRO's notice and invitation to meet regarding its findings, dated May 22, 1986 (A.R. 2338-39), the plaintiff gave no reason for not meeting with the board except that he felt he had done nothing improper for which to account. A.R. 2014. The plaintiff had advanced that his CME credits exceed the minimum for licensure, and that this fact evidences his willingness. A.R. 1986. But Dr. Moulton testified that this is not relevant, as many of those credits do not relate to the treatment of the problems that were the basis of the plaintiff's exclusion. A.R. 1742, 1744, 2494. Although the plaintiff testified that he would act differently in future cases, he stated he would do so only because Algoma Memorial Hospital no longer functions as a full-service hospital (it now requires that patients be transferred), and due to the threat of federal sanction. A.R. 2059-61. This evidence leads to the reasonable conclusion that the plaintiff has been unwilling and unable to comply substantially with his Social Security Act obligations. The Secretary has pointed to such relevant evidence as a reasonable mind may accept as adequate to support his conclusion on this issue.

4. Raising New Issues

The plaintiff raises certain issues in his complaint that he did not raise before the ALJ and the Appeals Council: (1) relating to the

burden of persuasion; (2) as to whether the actions of the OIG involve a program operating responsibility; (3) whether the fact that the OIG was a party to the administrative litigation and had investigative and supervisory functions violates the Administrative Procedure Act; and (4) whether the failure of the hearing procedures to provide for subpoena discovery authority violates due process.

The hearing in this action was conducted pursuant to the procedures set forth in 42 C.F.R. § 405.1530-.1595 (now 42 C.F.R. Part 498). The plaintiff, represented by counsel before the ALJ and the Appeals Council, had Dr. March testify for him pursuant to a subpoena issued by the ALJ at the plaintiff's request, A.R. 1285-88, and introduced the new evidence of patient L.M.'s affidavit to the Appeals Council. A.R. 3063. The parties entered into an Agreed Statement of Issues. A.R. 1289-93. The ALJ ruled on the burden of proof issue at a prehearing conference, A.R. 1281, and the parties were given the opportunity to object to the prehearing order. A.R. 1283. The ALJ ruled that the parties could "insert objections on procedural/constitutional issues in their closing briefs, in order to preserve them for appeal," A.R. 1281, and at the prehearing conference indicated that documents could be produced on any such issues to preserve them for appeal. A.R. 1350.

The plaintiff did not raise the issues on which he now offers argument before the ALJ or the Appeals Council. Despite the ALJ's burden of proof ruling and admonition regarding preserving issues and documents for appeal, the plaintiff failed to follow these dictates. Thus, while the plaintiff has presented lengthy argument on these issues, he has not submitted additional evidence through the proper channels on the questions that he would now have the Court decide. An issue not raised in the administrative phase of this action cannot be before this Court. *See* September 10, 1990 *Decision and Order* pp. 4-5. Accordingly, this Court must decline to consider the issues that the plaintiff raises in his complaint and on which he offers argument in his submissions.

Appendix B

B. Plaintiff's Reverse/Remand Motion

This Court has considered the arguments raised by the plaintiff in this motion in its resolution of the defendant's summary judgment motion, and found them unpersuasive. Because of the Court's resolution of that motion, it is unnecessary to repeat this analysis. The plaintiff's motion will be denied.

IV. SUMMARY

Under the foregoing reasoning, the Court GRANTS the defendant's summary judgment motion and DENIES the plaintiff's motion to reverse/remand. Dr. Papendick's two-year exclusion is upheld.

The Clerk of Court should enter judgment in this action pursuant to the conclusions in this opinion.

SO ORDERED this 26th, day of March, 1991, at Milwaukee, Wisconsin.

s/ Robert W. Warren
ROBERT W. WARREN
UNITED STATES DISTRICT JUDGE

APPENDIX C — SEPTEMBER 10, 1990, DECISION AND ORDER OF DISTRICT COURT GRANTING DEFENDANT PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Case No. 89-C-1005

DAVID E. PAPENDICK, M.D.
Plaintiff,

v.

LOUIS SULLIVAN, M.D., Secretary of Health and Human Services,
Defendant.

DECISION AND ORDER

The defendant's motion for a protective order pursuant to Fed.R.Civ.P. 26(c) and the plaintiff's request for oral argument on this motion are before the Court.

I. FACTUAL AND PROCEDURAL BACKGROUND

On December 23, 1986, the Office of the Inspector General ("OIG") within the Department of Health and Human Services ("HHS") determined that pursuant to 42 U.S.C. § 1320c-5(b), the plaintiff, Dr. David E. Papendick M.D., should not be authorized to receive reimbursement for treating Medicare patients for a period of two years commencing January 27, 1987.[1] The OIG judged that

---

1. For a portion of the OIG's decision, as well as a recitation of plaintiff's unsuccessful attempt to enjoin his exclusion in the United States District Court for the Western District of Wisconsin, see *Papendick v. Bowen*, 658 F. Supp. 1425, 1427-28 (W.D. Wis. 1987).

plaintiff had grossly and flagrantly violated his obligations under 1156 of the Social Security Act, 42 U.S.C. § 1320c-5, and that he had demonstrated an unwillingness or lack of ability to substantially comply with the obligations imposed by that section. The OIG notified plaintiff of his appeal rights pursuant to 42 U.S.C. 1320c-5(b)(4), which incorporates 42 U.S.C. § 405(g). Administrative Record pp. 2441-2447 (hereafter "A.R. ____."). Upon plaintiff's request, an administrative hearing took place in Madison, Wisconsin on May 28 & 29, 1987, and in Green Bay, Wisconsin on June 1 & 2, 1987. A.R. 1624-2336. Plaintiff, represented by counsel, presented witness and introduced exhibits. One of plaintiff's witnesses attended the hearing under a subpoena issued by the Administrative Law Judge ("ALJ") at plaintiff's request. A.R. 1285-88. On December 28, 1987, the ALJ upheld the two-year exclusion. A.R. 911-955. Plaintiff appealed to the Appeals Council, and submitted additional evidence. A.R. 2886-2889. On June 22, 1989 the Appeals Council affirmed the decision of the ALJ. A.R. 5-11. Plaintiff filed this action August 18, 1989. Plaintiff has propounded certain discovery requests for admissions and for the production of documents. *See* Exhibit A to Defendant's Memorandum in Support of Motion for Protective Order.

II. DISCUSSION

A. Request for Oral Argument

After perusal of the parties' submissions, the Court determines that the briefing on the motion for a protective order adequately treats the issues at bar. The time of the Court and counsel need not be expended arguing matters already covered. Accordingly, plaintiff's request for oral argument on the pending motion will be denied.

Appendix C

B. Protective Order

The federal statute under which the OIG excluded plaintiff from the Medicare program provides in part:

> Any practitioner or person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

42 U.S.C. § 1320c-5(b)(4). The scope of the judicial review referred to toward the end of this passage is delineated at 42 U.S.C. § 405(g), which partially provides:

> As part of his answer the Secretary shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the cause for a rehearing.

The defendant has filed his answer and a certified copy of the record. The hearings at which this record was compiled were conducted pursuant to 42 C.F.R. Part 498. These procedures provide for live testimony and the receipt of documentary evidence. They also authorize the ALJ to issue subpoenas for the attendance

and testimony of witnesses and for the production of relevant documentary evidence, provide for a party's request to disqualify the ALJ if he is prejudicial or partial (if the objections are presented at the earliest opportunity), and permit new relevant evidence to be admitted before the Appeals Council. *See* 42 C.F.R. § 405.1534, 405.1544-.1547, 405.1565 (1986).

The defendant correctly concludes that plaintiff's claims may be argued in this Court on the record below, and not on an additional record created in this Court. Section 405(g) review precludes a court "from considering evidentiary submissions outside of the pleadings and transcript of record in deciding whether the Secretary's decision ... should be modified, reversed, or affirmed." *Orlandi v. Weinberger*, 421 F. Supp. 586, 589 (E.D. Wis. 1976). *See also Flores v. Heckler*, 755 F.2d 401, 403 (5th Cir. 1985) (§ 405(g) only authorizes review of the pleadings and the record; district courts in § 405(g) cases may not consider evidence outside the administrative record); *Goodrich v. Heckler*, 628 F. Supp. 187, 189-90 (D. Conn. 1986) (district court grants Secretary's motion for protective order in § 405(g) case). Further, district courts are not to consider questions not presented in administrative proceedings below. *Myron v. Chicoine*, 678 F.2d 727, 731 (7th Cir. 1982) (providing authority and policy rationales for this proposition). This is also true with regard to alleged constitutional violations. *See Homewood Prof. Care Center Ltd. v. Heckler*, 764 F.2d 1242, 1249 (7th Cir. 1985) (constitutional claims first must be presented to HHS administrative body); *Weyerhauser Co. v. Marshall*, 592 F.2d 373, 376 (7th Cir. 1979) (agency should develop factual record for constitutional determination).

The defendant has correctly stated that plaintiff's discovery requests involve the actions of the OIG if plaintiff had raised the claims in Counts III-V of the Complaint. A failure to raise these issues below cripples plaintiff's attempt to obtain discovery on

them now under the doctrines of waiver and exhaustion of administrative remedies. *See* Defendant's Memorandum in Support of Motion for Protective Order pp. 7-8. The plaintiff argues that no provisions exist for considering constitutional issues or challenges to the administrative procedures in use. Plaintiff asserts that once the defendant responds to the requested discovery, the Court can render a determination on the defendant's policy and practice, and that plaintiff therefore does not need to exhaust his administrative remedies. Plaintiff reasons that § 405(g) does not preclude judicial review (and therefore discovery toward the end of developing a factual record on which to predicate that review) of collateral issues "when the administrative hearing does not provide for discovery and the position of the Secretary's delegated representative, the Inspector General, is that the ALJ does not have authority to consider the issues raised herein." Plaintiff's Memorandum in Opposition to Motion for Protective Order p. 8.

Plaintiff's reasoning here fails in the face of a number of points: (1) assuming plaintiff is correct that the OIG would have objected to consideration of the issues raised in plaintiff's discovery requests, the ALJ and Appeals Council would not have been precluded from ruling on their jurisdiction over such issues, or in the alternative allowing plaintiff to compile a record; (2) plaintiff never gave the ALJ and the Appeals Council the chance to consider the issues raised in his discovery requests to preserve those issues for review; (3) although 42 C.F.R. Part 498 does not provide for prehearing discovery, the hearing procedures do provide for subpoenas for production of witnesses and documents at the hearing itself, which plaintiff availed himself of on other issues, but not those issues on which he now seeks discovery; and (4) plaintiff's discovery requests seek more than to raise collateral or procedural issues, for they seek to compile extrarecord evidence concerning these issues; *see Good Samaritan Medical Center v. Secretary of HHS*, 776 F.2d 594, 598-99 (6th Cir. 1985) (court holds

parties must raise issues and compile record concerning collateral procedural issues in the administrative forum regardless of whether administrative forum can provide complete relief).

Title 42 U.S.C. § 1320c-5(b)(4) provides for "judicial review of the Secretary's final decision after such hearing as is provided in [§]405(g)." Under § 405(g), plaintiff requested and received a *de novo* evidentiary hearing before an ALJ at which through counsel he could raise issues, submit evidence, and subpoena witnesses and documents. 42 C.F.R. Part 498. Section 405(g), which governs this Court's review of this matter, provides that the court's review and decision shall be based on the "transcript of the record." Therefore, these relevant federal statutes dictate that this Court's jurisdiction is limited to review and decision on the record of testimony, exhibits, and issues submitted and compiled in the administrative forum, along with the particular findings and conclusions regarding these submissions advanced by the Secretary – through the ALJ and Appeals Council – in support of his final administrative decision.

As the defendant has stated: "This Court . . . is not the trier of fact (and cannot reweigh the facts established below), nor is this an evidentiary proceeding." Defendant's Reply Memorandum in Support of Motion for Protective Order p. 6. Fed.R.Civ.P. 26(c) provides in relevant part:

> Upon motion by a party . . . and for good cause shown, the court in which the action is pending . . . may make any order which justice requires to protect a party . . . from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following: (1) that discovery not be had; . . . (4) that certain matters not be inquired into, or that the scope of the discovery be limited to certain matters; . . . .

Appendix C

Because plaintiff's discovery requests are not contemplated by the statutory review that this Court undertakes as its role in this action, defendant's motion for a protective order pursuant to Rule 26(c) will be granted.

III. SUMMARY

Based on the foregoing reasoning, the Court DENIES plaintiff's request for oral argument on the pending motion, and GRANTS the defendant's motion for a protective order pursuant to Fed.R.Civ.P. 26(c) as to Plaintiff's First Request for Admissions under Rule 36 and Production of Documents under Rule 34. As for the further prosecution of this action, the parties are to adhere to the following briefing schedule: dispositive motions are to be filed within the next 60 days; further briefing should follow Local Rule 6.01.

SO ORDERED this 10th day of September, 1990, at Milwaukee, Wisconsin.

s/ Robert W. Warren
ROBERT W. WARREN
UNITED STATES DISTRICT JUDGE

APPENDIX D — DECEMBER 23, 1986, NOTICE OF EXCLUSION ISSUED BY OIG OFFICIAL JAMES PATTON TO DR. DAVID E. PAPENDICK, M.D.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

DEC. 23, 1986

DAVID E. PAPENDICK, M.D.
801 4th Street
Algoma, Wisconsin 54201

Dear Dr. Papendick:

This letter is to notify you that a determination has been made that you be excluded from participating in the Medicare program for a period of 2 years, pursuant to the authority set out in section 1156 of the Social Security Act, 42 U.S.C. §1320c-5. A copy of the material submitted to me and which formed the basis for this decision was previously furnished to you by the Wisconsin Peer Review Organization, the Peer Review Organization (PRO) for Wisconsin, and is hereby incorporated in this notice by specific reference. (Copy enclosed.)

By letter dated August 26, 1986, you were notified by the PRO that a recommendation had been submitted to the Office of the Inspector General (OIG) that you be excluded from participation in the title XVIII (Medicare) program for a period of 12 years.

The PRO's recommendation is based on its determination that in two cases involving five hospital admission you grossly and flagrantly violated the obligations imposed on you by section 1156(a) of the Social Security Act to provide care that meets professionally recognized standards of quality. The specific case numbers identified by the PRO were numbers [. . .] and [. . .].

Appendix D

The PRO's letter of August 26, 1986 afforded you the opportunity to submit to the OIG any additional material you believed would affect the PRO's recommendation to exclude you from the Medicare program. The additional material submitted on your behalf was received by this office on October 6, 1986.

After a careful review of all the evidence of record, and acting on the authority delegated to me by the Inspector General of the Department of Health and Human Services, I have determined that I agree with the conclusion of the PRO that in the case numbers cited above you grossly and flagrantly violated your obligations under section 1156.

I have also determined that you have demonstrated a lack of ability substantially to comply with the obligations imposed on you by section 1156(a) of the Social Security Act. This is evidenced by your failure to recognize the danger in your failure to obtain appropriate and timely consultations, as well as the use of multiple drugs in the treatment of cardiac arrhythmias and your failure to transfer a patient to a teriary care facility in a timely manner.

On the basis of my agreement with the PRO's conclusion in two cases that you have failed to comply with your obligations under section 1156(a) and my determination that you have demonstrated an unwillingness of lack of ability substantially to comply with these obligations, all items and services ordered or furnished by you will be excluded from reimbursement under the Medicare program for a period of 2 years.

In arriving at the period of exclusion, I have considered, as required by 42 CFR 1004.90(d), the following information:

1. The recommendation of the PRO:

   The Wisconsin Peer Review Organization recommended you be excluded for 12 years.

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2. The type of offense:

   You grossly and flagrantly violated your obligations under section 1156(a) in two cases involving five hospital admissions.

3. Severity of the offense:

   In the two cases cited your treatment presented an imminent danger to the health, safety, or well-being of the beneficiaries involved.

4. The previous sanction record of the practitioner or other person:

   I am unaware of any previous sanction record.

5. The availability of alternative sources of services in the community:

   There is one other general practitioner and one family practitioner servicing Algoma, Wisconsin.

6. Any prior problems the Medicare carrier or intermediary has had with the practioner or other person:

   I am unaware of any prior problems identified by the Medicare carrier or intermediary.

7. Whether the practioner or other person is unable or unwilling to comply substantially with the obligations:

   As stated previously in this letter, I have determined that your

failure to recognize the danger in your not obtaining appropriate and timely consultations, using multiple drugs in the treatment of cardiac arrhythmias and failing to transfer a patient to a teriary care facility in a timely manner constitute an inability to comply with your obligation under section 1156.

8. Any other matters relevant to the particular case:

I am unaware of any other issues relevant to this case.

The authority for this determination is contained in section 1156(b)(1) of the Social Security Act (42 U.S.C. §1320c-5(b)(1)). This exclusion will be effective 15 days from the date of receipt of this letter. The date of receipt is presumed to be five days after the date of this letter, unless there is a reasonable showing to the contrary. As of that date, Medicare will no longer make payment for items or services ordered or furnished by you. As specified in 42 CFR 1004.100(d), we will place a notice in a local newspaper to advise the community of the effective date, the duration, and the reason for this exclusion.

If you do not believe this decision is correct, you may request a hearing before an Administrative Law Judge of the Social Security Administration. To be effective, a written request for a hearing must be filed no later than 60 days from the date you receive this letter. The request for a hearing shall contain the specific issues or findings of fact and conclusions of law with which you disagree, and the basis for the contention that the specific issues and/or findings and conclusions were incorrect. Evidence and arguments may be presented at the hearing and you may be represented by counsel. Such a request should be sent to the Office of the Inspector General, Office of Investigations, Room 1-A-3, Meadows East Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Appendix D

At the conclusion of the 2-year period, or anytime thereafter, you may be eligible for reinstatement to the program. If you wish to seek reinstatement, you should apply in writing to the Office of the Inspector general at least 90 days prior to the date of reinstatement for which you are petitioning. At that time, you will be advised of the information required for us to reach a decision on your reinstatement.

Sincerely yours,

s/ James F. Patton
JAMES F. PATTON
Director
Health Care Administrative Sanctions
Office of Investigations

Enclosure
cc:
Regional Inspector General, OI
Chicago
Health Services Administration
Public Health Services
Office of General Counsel
Inspector General Division
Department of Labor
Office of Public Affairs

APPENDIX E — MAY 27, 1987, ADMINISTRATIVE LAW JUDGE REPORT OF PREHEARING CONFERENCE AND ORDER

OFFICE OF HEARINGS AND APPEALS
SOCIAL SECURITY ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Docket No. 000-54-7038

In the Matter of:

David E. Papendick, M.D.

Petitioner

Appeal of Sanction Imposed Pursuant to Section 1156 of the Social Security Act

REPORT OF PREHEARING CONFERENCE AND ORDER

I. Report of Prehearing Conference.

A. The undersigned held a prehearing conference in this matter on May 8, 1987 in Chicago, Illinois. In attendance were:

Jeff Scott Olson, Esquire of Julian and Olson S.C. Attorney for Petitioner David E. Papendick, M.D.

Laurence Gilbert, Assistant Regional Counsel, Attorney for Respondent Office of Inspector General (OIG).

Barbara Wright, Attorney Advisor, Office of Hearings and Appeals.

David E. Papendick, M.D. Petitioner

Appendix E

B. Issues.

The parties agreed that the general issues before the undersigned are:

1. Did Petitioner violate the provisions of section 1156 of the Social Security Act?

2. If such a violation occured, what, if any, is the appropriate sanction?

Several sub-issues were also noted and/or discussed:

1. The care at issue in this proceedings.

   The parties agreed that only the care of the patients referred to in charts nos. F3120, F3155, F3276, F3305 and F3752 (Exhibits B-7, B-8, B-9, B-10 and B-11) are at issue. Any inadvertent reference to the care of other patients in the exhibits of record is to be disregarded.

2. Petitioner's willingness and ability to comply with his statutory obligations under section 1156 of the Act.

3. Whether a favorable finding as to Petitioner's willingness and ability to comply with his statutory obligations would preclude the imposition of an exclusionary sanction (i.e. limit any potential sanction to a monetary assessment).

4. The parties agreed that should Petitioner's violations *not* be found "gross and flagrant" the number of cases involved does not constitute a "substantial" number and thus there would be no actionable vilation of section 1156 of the Act [see pages 42, 43, and 44 of the prehearing transcript].

Appendix E

5. The standard of care at issue.

   Is the standard of care applied a local, regional or statewide standard?

C. Exhibits.

* * *

D. Witnesses/Testimony

* * *

E. Stipulations.

* * *

F. The undersigned also made numerous rulings affecting other aspects of this case:

   1. Designation of Parties.

* * *

   2. Burden of Persuasion.

* * *

   3. The undersigned has no jurisdiction to rule on constitutional issues. The parties may however insert objections on procedural/constitutional issues in their closing briefs, in order to preserve them for appeal.

Appendix E

4. * * *

5. Opening statements and closing statements may be waived.

* * *

6. * * *

7. * * *

8. PRO Manual/OIG Manual.

* * *

9. Confidentiality.

* * *

10. 42 CFR 1004.130(a)(2)

* * *

11. Citations to decisions or orders of the Appeals Council or other Administrative Law Judges.

* * *

12. Reliance on medical texts.

Appendix E

* * *

II. It is hereby ordered as follows:

* * *

s/ Stephen Jon Ahlgren
STEPHEN JON AHLGREN
Administrative Law Judge

Date: 5/27/87

APPENDIX F— JUNE 22, 1989, COVER LETTER CONFIRMING APPEALS COUNCIL AFFIRMATION OF PETITIONER'S EXCLUSION

June 22, 1989

David E. Papendick, M.D.
801 4th Street
Algoma, WI 54201

Dear Dr. Papendick:

Enclosed is a copy of the decision of the Appeals council on your exclusion from participation in the Medicare program under the Social Security Act.

If you desire a court review of the Appeals Council's decision, you may commence a civil action by filing a complaint in the United States District Court for the judicial district in which you reside within sixty (60) days from the date of receipt of this letter. It will be presumed that this letter is received within five (5) days after the date shown above unless a reasonable showing to the contrary is made. The complaint should name the Secretary of Health and Human Services as the defendant and should include the Social Security number(s) shown at the top of this notice. The right to court review is provided for in sections 205(g) and 1156(b)(4) of the Social Security Act, as amended (42 U.S.C. 405(g) and 1320c-5).

If a civil action is commenced, the Secretary must be served by sending a copy of the summons and complaint by registered or certified mail to the General Counsel of the Department of Health and Human Services at 200 Independence Avenue, S.W., Washington, D.C. 20201. (See Rules 4(c)(2) and (d)(4) and (5) of the Federal Rules of Civil Procedure and Part 45, Section 4.1 of the

code of Federal Regulations.) In addition, you must serve the United States Attorney for the district in which you file your complaint and the Attorney General of the United States, as provided in the Federal Rules of Civil Procedure.

Sincerely yours,

s/ William Raffel
WILLIAM RAFFEL
Member, Appeals Counsel

Enclosure

cc:
HO, Milwaukee, WI (ALJ Ahlgren)
RCALJ, Chicago, IL
Mr. James F. Patton
Michael Dyer, Esq.
Jeff Scott Olson, Esq.
Laurence Gilbert, Esq.

APPENDIX G — FEBRUARY 7, 1989, NOTICE OF REINSTATEMENT ISSUED BY OIG OFFICIAL JAMES PATTON TO DR. DAVID E. PAPENDICK, M.D.

FEB 7 1989

Mr. Jeff Scott Olson
Attorney at Law
Julian, Olson, and Lasker
Post Office Box 2206
Madison, Wisconsin 53701-2206

Dear Mr. Olson:

RE: David E. Papendick, M.D.
801 4th Street
Algoma, Wisconsin 54201

Your request for the reinstatement of your client, David E. Papendick, M.D., as a provider of services covered by the title XVIII (Medicare) program has been approved. Dr. Papendick's reinstatement is effective with the date on this notice.

We have notified the Wisconsin Department of Health and Social Services of this action. However, the State is not obligated to reinstate Dr. Papendick to the Medicaid program if it has imposed a longer period of exclusion under its own authority.

We recommend that Dr. Papendick contact the Medicare carrier to determine his options for participating in that program.

We will place a legal notice in a local newspaper to inform the public of the withdrawal of Dr. Papendick's exclusion under title XVIII of the Social Security Act.

Appendix G

Sincerely yours,

s/ James F. Patton
JAMES F. PATTON
Director
Health Care Administrative Sanctions
Office of Investigations

APPENDIX H — PERTINENT PORTION OF JAMES F. PATTON'S PERFORMANCE PLAN FOR FISCAL YEAR OCTOBER 1, 1985 TO SEPTEMBER 30, 1986

PERFORMANCE PLAN

PERFORMANCE PLANNING, REVIEW AND APPRAISAL SYSTEM

Employee's Name: *James F. Patton*

For Performance Period: *October 1, 1985* to *September 30, 1986*

Supervisor's Name: *Eileen Boyd*

Organization: *DHHS, OS, OIG, Office of Investigations*

Employee's Title: *Director, Division of Health Care Administrative Sanctions*

GM Series and Grade (if applicable) *GM-15*

* * *

NAME: *James F. Patton*

Objective No 2 Of 3	[X] Check if Critical Critical	Weight (Points) 40

Case Management (Program Integrity) — Increase the deterrence of fraud and abuse in our health care programs through the identification of wrongdoers and through successful sanctioning. Measurement of this objective is in: (1) the number of successful

health care provider administrative sanctions documented, (2) the amount of dollar assessments successfully assigned to health providers found to have engaged in fraud and abuse as a result of Civil Monetary Penalty or legal actions.

* * *

Level 3 (Required for Merit Pay)

Exceeded by 10 percent number of successful sanctions, and dollar penalties.

Level 2 (Required for Merit Pay and SES)

As direct result of HFI reviews and investigations: (1) the number of successful health provider sanctions will be 330, and (2) dollar penalties successfully assigned administratively and legally against wrongdoers equaled $12 million.

* * *

APPENDIX I — PERTINENT PORTION OF *KENNETH MELASHENKO, M.D. V. BOWEN*, CV-F-87-533, 1990 W.L. 159905, (E.D.CAL.)

Not Reported in F.Supp. R 1 OF 1
Medicare & Medicaid Guide P 38, 827
(CITE AS: 1990 WL 159905 (E.D.Cal.))

Kenneth MELASHENKO, M.D.
v.
BOWEN.
No. CV-F-87-533.
United States District Court, E.D. California
June 19, 1990.

COYLE, District

*1 On September 25, 1989, the court heard plaintiff's Motion for Permanent Injunction and Order to Show Cause. Upon due consideration of the written and oral arguments of the parties, the court now enters its order denying the Order to Show Cause and granting the Permanent Injunction in part, as set forth herein. Plaintiff also moves, pursuant to Rule 15(d) of the Federal Rules of Civil Procredure, to Supplement his Reply. The parties waived oral argument on this motion, and the court now enters its order granting the motion to supplement in part, and denying it in part, as set forth herein.

1. Facts

Dr. Melashenko was excluded from participating in the Medicare program. On September 22, 1987 this court issued a Temporary Restraining Order prohibiting the Department of Health and Human Services from suspending or excluding

Appendix I

Melashenko pending administrative review of the decision to exclude him. On November 30, 1987 the court denied Melashenko's motion for a preliminary injunction. The court explained this decision in its January 22, 1988 Memorandum Decision Re: Motion for Preliminary Injunction (the "Order"). On March 4, 1988 the court denied Melashenko's motion for an injunction pending appeal.

Melashenko appealed the exclusion decision to an administrative law judge (ALJ). The ALJ handed down his decision on January 27, 1989. The ALJ decision represented a qualified victory for Melashenko — the Office of Inspector General ("OIG") had sought to exclude Melashenko for 5 years, but the ALJexcluded Melashenko for only 6 months — 6 months which the ALJ knew had already elapsed. The OIG appealed the ALJ decision.

The ALJ stated that Melashenko should be reinstated promptly to the Medicare program. Melashenko applied for reinstatement in early February of 1989. After several months delay, the OIG refused to reinstate Melashenko. On July 7, 1989, Melashenko asked the OIG to reconsider its denial. While the OIG was evaluating this request, Melashenko returned to this court to seek a permanent injunction, pursuant to Rule 65 of the Federal Rules of Civil Procedure and 28 U.S.C. ss 1365 and 2201, preventing the OIG from using the process used to exclude him, and baring his own exclusion. Melashenko also sought an order to show cause regarding his reinstatement. This motion is moot because the OIG has since reinstated Melashenko to the Medicare program.

* * *

Appendix I

(vi) Bias.

Accordining to Melashenko, the OIG hearing violated his due process rights because the decision-maker, Patton, was biased. Melashenko claims that Patton was biased because he served multiple roles — investigator, prosecutor, and judge — and because the merit pay/bounty system then in place at the OIG gave Patton a pecuniary interest in the outcome of the hearing.

Generally, separation of the roles of investigator, prosecutor, and judge is desirable. However, intermingling of these roles does not necessarily violate due process. In Withrow v. Larkin, 421 U.S. 95 (1975), the United States Supreme Court found that the fact that an examining board had multiple functions did not alone violate a physician's right to due process in a suspension proceeding under a Wisconsin statute. Therefore, the court finds that Patton's multiple role did not deprive Melashenko of due process.

It is clear from Patton's testimony before the ALJ that Patton, who played a significant role in making the decision to exclude Melashenko, was eligible to receive merit pay based on the number of sanctions he imposed. The United States Supreme Court has held that where a decisionmaker has a pecuniary interest in the outcome of the decision, the "probability of actual bias on the part of the judge or decisionmaker is too high to be constitutionally tolerable." Withrow v. Larkin, 421 U.S. 35, 47 (1975). Because of the merit pay system, Patton had a pecuniary interest in deciding against Melashenko. This plainly deprived Melashenko of due process, and the OIG practice of awarding merit pay to the decisionmaker based on the outcome of the decision must be enjoined. [FN2]

Appendix I

3. Motion to Supplement Reply.

Melashenko moves, pursuant to F.R.C.P. Rule 15(d), to supplement their reply brief by including in the record a letter from James Patton dated September 19, 1989 and a letter to this court from the California Medical Association (the "CMA"). Defendants do not object to the inclusion of the Patton letter, and the court thus grants Melashenko's motion to supplement his reply by including the Patton letter in the record.

The government strenuously objects to the inclusion of the CMA letter in the record. The court agrees. The CMA is not a party to this action and has never been involved in any way with these proceedings. As the government argues, the CMA letter contains many important factual representations and inclusion of the letter in the record would prejudice the government which would have no opportunity for discovery or rebuttal. Finally, Rule 15(d) concerns amendment of pleadings, not reply briefs, and only applies to "transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." The CMA letter is not a transaction, occurrence or event of the sort contemplated by Rule 15(d). For all of these reasons, the court denies Melashenko's motion to supplement his reply brief by inclusion of the CMA letter in the record.

*5 ACCORDINGLY, IT IS ORDERED that the OIG is permanently enjoined from awarding merit pay to a pre-exclusion due process hearing decisionmaker if the merit pay is based upon the outcome of the decision.

IT IS FURTHER ORDERED that the exclusion of plaintiff from the Medicare program is vacated, and the OIG is permanently enjoined from excluding plaintiff from the Medicare program

based on the pre-exclusion OIG hearing or subsequent procedures.

IT IS ALSO ORDERED that plaintiff's Motion to Supplement the Reply is granted in part and denied in part.

FN1. This applies to other procedures provided under other statutes which Melashenko claims the OIG must follow to provide due process, including educational and persuasive contacts, giving the physician a chance to reform, and using exclusion as a last resort.

FN2. At oral argument, government counsel stated that the OIG no longer used such merit pay/bounty system. However, defendants put forth no evidence that the OIG had discontinued the practice, and the court therefore assumes that it is still in place.

APPENDIX J — PERTINENT PORTION OF ADMINISTRATIVE RECORD, TESTIMONY OF DR. JONATHON MOULTON, M.D., PRO WITNESS (A.R. 1820) MAY 28, 1987, BEFORE ADMINISTRATIVE LAW JUDGE AHLGREN

* * *

It is our obligation – part of it's the payment sytem. If we don't initiate – if we don't send out a letter of initial termination, we have to pay for all the subsequent investigation. If we list – if we send out a letter of sanction initially, than the Federal Government starts picking up the costs as part of the sanction proceeding, so that's the way it's done.

Q. Do you recall ever knowing whether Dr. Papendick gave reason for why he did not come to the meeting on the

* * *

APPENDIX K – RELEVANT CONSTITUTIONAL PROVISIONS AND STATUTES INVOLVED

United States Constitution, Fifth Amendment:

AMENDMENT V – GRAND JURY INDICTMENT FOR CAPITAL CRIMES; DOUBLE JEOPARDY; SELF-INCRIMINATION; DUE PROCESS OF LAW; JUST COMPENSATION FOR PROPERTY

No person shall

* * *

be deprived of life, liberty, or property, without due process of law;

* * *

42 U.S.C. § 405(b):

(b) Administrative determination of entitlement to benefits; findings of fact; hearings; investigations; evidentiary hearings in reconsiderations of disability benefit terminations; subsequent applications

(1) The Secretary is directed to make findings of fact, and decisions as to the rights of any individual applying for a payment under this subchapter. Any such decision by the Secretary which involves a determination of disability and which is in whole or in part unfavorable to such individual shall contain a statement of the case, in understandable language, setting forth a discussion of the evidence, and stating the Secretary's determination and the reason

or reasons upon which it is based. Upon request by any such individual or upon request by a wife, divorced wife, widow, surviving divorced wife, surviving divorced mother, surviving divorced father, husband, divorced husband, widower, surviving divorced husband, child, or parent who makes a showing in writing that his or her rights may be prejudiced by any decision the Secretary has rendered, he shall give such applicant and such other individual reasonable notice and opportunity for a hearing with respect to such decision, and, if a hearing is held, shall, on the basis of evidence adduced at the hearing, affirm, modify, or reverse his findings of fact and such decision.

* * *

42 U.S.C. § 405(g):

(g) Judicial Review

Any individual, after any final decision of the Secretary made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision or within such further time as the Secretary may allow.

* * *

As part of his answer the Secretary shall file a certified copy of the transcript of the record including the evidence upon which the findings and decision complained of are based. The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the Secretary, with or without remanding the cause for a rehearing. The

findings of the Secretary as to any fact, if supporting by substantial evidence, shall be conclusive, and where a claim has been denied by the Secretary or a decision is rendered under subsection (b) of this section which is adverse to an individual who was a party to the hearing before the Secretary, because of failure of the claimant or such individual to submit proof in conformity with any regulation prescribed under subsection (a) of this section, the court shall review only the question of conformity with such regulations and the validity of such regulations.

* * *

42 U.S.C. § 1320c-5:

Obligations of health care practitioners and providers of health care services; sanctions and penalties; hearings and review

* * *

(b) Sanctions and penalties; hearings and review

(1) If after reasonable notice and opportunity for discussion with the practitioner or person concerned, and, if appropriate, after the practitioner or person has been given a reasonable opportunity to enter into and complete a corrective action plan (which may include remedial education) agreed to by the organization, and has failed successfully to complete such plan, any organization having a contract with the Secretary under this part dtermines that such practitioner or person has —

(A) failed in a substantial number of cases substantially to comply with any obligation imposed on him under subsection (a) of this section, or

(B) grossly and flagrantly violated any such obligation in one or more instances.

such organization shall submit a report and recommendations to the Secretary. If the Secretary agrees with such determination and determines that such practitioner or person, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this chapter, has demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, the Secretary (in addition to any other sanction provided by law) may exclude (permanently or for such period as the Secretary may prescribe) such practitioner or person from eligibility to provide services under this chapter on a reimbursable basis. In determining whehter[1] [sic] a practitioner or person has demonstrated an unwillingness or lack of ability substantially to comply with such obligations, the Secretary shall consider the practitioner's or person's willingness or lack of ability, during the period before the organization submits its report and recommendations, to enter into a successfully complete a corrective action plan.

* * *

42 C.F.R. § 498.82:

§ 498.82 Request for Appeals Council review.

* * *

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

Appendix K

42 C.F.R. § 1004.60:

§ 1004.60 Final PRO determination of a violation.

If the issue is not resolved to the PRO's satisfaction as specified in § 1004.50(c), the PRO must —

(a) Submit its report and recommendation to the OIG; and

* * *

42 C.F.R. § 1004.90:

Subpart — OIG Responsibilities

§ 1004.90 Acknowledgement and review of report.

* * *

(b) *Review.* The OIG will review the PRO report and recommendation to determine whether —

(1) The PRO is following its procedures:

(2) A violation has occurred; and

(3) The practitioner or other person has demonstrated an unwillingness or lack of ability substantialiy to comply with an obligation.

* * *

Appendix K

(d) *Decision of sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriatesanction by considering —

(1) The recommendation of the PRO;

(2) The type of offense;

(4) The previous sanction record of the practitioner or other person;

(5) The availability of alternative sources of services in the community;

(6) Any prior problems the Medicare carrier or intermediary has had with the practitioner or other person;

(7) Whether the practitioner or other person is unable or unwilling to comply substantially with the obligations; and

(8) Any other matters relevant to the particular case.

* * *

42 C.F.R. § 1004.100:

§ 1004.100 Notice of sanction.

(d) The OIG notifies the public by publishing in a newspaper of general circulation in the PRO area a notice that identifies the sanctioned practioner or other person, the obligation that has been violated, the sanction imposed and, if the sanction is exclusion, the effective date and duration.

(e) Notice of the sanction is also provided to the following entities as appropriate:

(1) The PRO that originated the sanction report.

(2) PROs in adjacent areas.

(3) State Medicaid fraud control units and State licensing bodies.

(4) Appropriate Medicare contractors and State agencies.

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations (HMOs).

(6) Medical societies and other professional organizations.

(7) Medical carriers and intermediaries, health care prepayment plans, and other affected agencies and organizations.

* * *

42 C.F.R. § 1004.120:

§ 1004.120 Reinstatement after exclusion.

Exclusion will remain in effect until —

(a) The OIG determines, in accordance with §§ 1001.130 through 1001.136 of this chapter, that the basis for the exclusion no

longer exists and there is reasonable assurance that the problems will not recur, or

(b) The OIG's determination to exclude is reversed by a hearing decision.

42 C.F.R. § 1005.21:

§ 1005.21 Appeal to DAB.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions, which may raise any relevant issue not addressed in the exceptions within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

* * *

(e) The DAB will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

* * *

APPENDIX L — FEDERAL REGISTER/VOL. 57, NO. 19/ WEDNESDAY JANUARY 29, 1992/RULES AND REGULATIONS 3325

J. Part 1005 — Appeals of Exclusions and CMP's

General Comments:

* * *

Response:

* * *

With respect to the objection to § 1005.4(c), we note that the ALJ's own authority in these proceedings is derived from the Secretary by delegation (sections 1128A(f) and 205(b) of the Act). Since the ALJ's authority to hear cases comes from the Secretary, the ALJ cannot overrule acts of the Secretary which may have an impact on these cases. The full scope of the ALJ's limited authorities in these proceedings is contained in § 1005.2.

* * *

(2)

No. 92-652

Supreme Court, U.S.
FILED
DEC 16 1992
OFFICE OF THE CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1992

DAVID E. PAPENDICK, PETITIONER

v.

LOUIS W. SULLIVAN, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

The Secretary of Health and Human Services excluded petitioner, a physician, from receiving reimbursement under the Medicare program for a two-year period. The question presented is whether, in reviewing the Secretary's decision, the district court was required to consider claims that petitioner did not advance in administrative proceedings.

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BRIEF FOR THE RESPONDENT IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-8a) is reported at 969 F.2d 298. The opinion of the district court (Pet. App. 9a-23a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 17, 1992. The petition for a writ of certiorari was filed on October 14, 1992. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. Section 1156 of the Social Security Act requires physicians and other health care practitioners who provide services under the Medicare

program to assure that the services (1) are furnished economically and only when, and to the extent, medically necessary; (2) are of a quality that meets professionally recognized standards of health care; and (3) are supported by adequate evidence of medical necessity and quality. 42 U.S.C. 1320c-5(a); see also 42 C.F.R. 1004.10. To ensure that practitioners meet their obligations under Section 1156, the Secretary of Health and Human Services contracts with peer review organizations (PROs) to assess the medical necessity and quality of the Medicare services provided by practitioners in specific geographic areas. 42 U.S.C. 1320c-2, 1320c-3(a); see 42 C.F.R. 1004.30(b).[1]

If a PRO determines that a practitioner has violated his or her obligations under Section 1156, the PRO must then determine whether the violations involved either a "substantial" failure to comply with Section 1156 "in a substantial number of cases" or are "gross and flagrant" in nature. 42 C.F.R. 1004.40; see 42 U.S.C. 1320c-5(b)(1).[2] In either situation, the PRO must send written notice advising the practitioner of its determination, the basis for it, and the sanction that the PRO will recommend to the Office of the

---

[1] A PRO is either "composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area" or "has available to it * * * the services of a sufficient number of licensed doctors of medicine or osteopathy * * * in such area." 42 U.S.C. 1320c-1(1).

[2] The Secretary has defined a "[g]ross and flagrant violation" of Section 1156 to mean a violation that "presents an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations." 42 C.F.R. 1004.1(b).

Inspector General (OIG) in the Department of Health and Human Services (HHS). 42 C.F.R. 1004.40(b), 1004.50. The written notice informs the practitioner that he or she may, within 30 days, submit additional information in writing and request a meeting with the PRO to discuss its initial determination. 42 C.F.R. 1004.50(a)(5). If, after considering any additional information, the PRO makes a final determination that a practitioner has committed substantial violations in a substantial number of cases or one or more gross and flagrant violations, the PRO submits a report of its final determination and a sanction recommendation to the OIG. 42 U.S.C. 1320c-5(b); 42 C.F.R. 1004.60(a), 1004.70. Sanctions may include monetary penalties and exclusion of the practitioner from receiving Medicare reimbursement for a specified period. 42 U.S.C. 1320c-5(b)(1) and (3); 42 C.F.R. 1004.1(b), 1004.20, 1004.70(c).[3]

The OIG determines whether the practitioner has violated Section 1156 and, if so, whether the practitioner has "demonstrated an unwillingness or lack of ability substantially to comply" with Section 1156. 42 U.S.C. 1320c-5(b)(1); 42 C.F.R. 1004.90(b). Before the OIG makes those determinations, the practitioner may submit "additional written material or documentary evidence." 42 C.F.R. 1004.60(b)(2). If the OIG agrees that a practitioner has violated his or her statutory obligations, it decides on an appropriate sanction, based upon, among other things, the PRO's

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[3] The PRO bases the recommended sanction on the type of violations, their severity, the deterrent effect of the sanction, and the availability of alternative health care services in the community. 42 C.F.R. 1004.80.

recommendation, the type and severity of the violation, and whether the practitioner is unable or unwilling to comply substantially with the obligations. 42 C.F.R. 1004.90(d). Any period of exclusion imposed as a sanction takes effect 15 days after the practioner receives the OIG's decision. 42 C.F.R. 1004.100(f)(1).

If the practitioner is dissatisfied with the OIG's determination and sanction, he or she may obtain an evidentiary hearing before an administrative law judge. 42 C.F.R. 1004.130(a)(1).[4] At the hearing, the practitioner may call witnesses, submit briefs and documentary evidence, and present oral argument. 42 C.F.R. 498.58-498.63. If the practitioner is dissatisfied with the ALJ's decision, he or she may request review by the Appeals Council. 42 C.F.R. 1004.130 (a)(1). Following an adverse decision by the Appeals Council, the practitioner may seek "judicial review of the Secretary's final decision * * * as is provided in section 405(g) of [title 42]." 42 U.S.C. 1320c-5(b)(4).[5]

b. Petitioner is a general practice physician in Algoma, Wisconsin. In May 1986, the Wisconsin Peer Review Organization (WIPRO) sent petitioner a letter stating its initial determination that in three cases petitioner had grossly and flagrantly violated

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[4] 42 C.F.R. 1004.130(a)(1) incorporates the hearing procedures set forth in 42 C.F.R. Pt. 498. At the time of the hearing in the present case, those procedures were set forth in 42 C.F.R. Pt. 405, Subpt. O (1986). See 52 Fed. Reg. 22,446 (1987).

[5] The preclusion in 42 U.S.C. 405(h) of other avenues of judicial review also applies to proceedings under 42 U.S.C. 1320c-5. 42 U.S.C. 1320a-7(f)(3).

his obligations under Section 1156.[6] The letter identified the three cases, each of which involved a different patient, and the records on which the initial determination was based. The letter also informed petitioner that WIPRO intended to recommend that he be excluded from the Medicare program for 12 years. Finally, the letter told petitioner that within 30 days he could submit additional information in writing or request a meeting with WIPRO, or both. Pet. App. 1a-2a, 11a, 13a-20a; see also *Papendick* v. *Bowen*, 658 F. Supp. 1425, 1426-1427 (W.D. Wis. 1987).

Petitioner declined to request a meeting with WIPRO. Instead, he sent WIPRO a letter disputing WIPRO's characterization of the medical care he provided in the three cases identified in the initial determination. Petitioner also submitted documents and tape recordings from prior proceedings before a PRO; none of that material, however, concerned the three patients at issue in this proceeding. Pet. App. 2a, 20a-21a; *Papendick*, 658 F. Supp. at 1427.

On August 26, 1986, WIPRO recommended to the OIG that petitioner be barred from the Medicare program for a twelve-year period. Petitioner sent a letter to the OIG, accompanied by documentary evidence, arguing that exclusion was not warranted. Based on those submissions, on December 23, 1986, the OIG found that petitioner had grossly and flagrantly violated his statutory obligations by providing care to two cardiac patients, identified as H.D. and L.M., that did not meet professionally recognized standards. The OIG also determined that,

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[6] WIPRO later decided not to pursue one of the cases identified in its initial determination.

as a sanction, petitioner should be barred from receiving Medicare reimbursement for a two-year period (rather than the twelve-year period recommended by WIPRO). Pet. App. 2a, 11a, 24a-25a; *Papendick*, 658 F. Supp. at 1427-1428.

Petitioner sought a hearing before an ALJ. In a Report of Prehearing Conference and Order, the ALJ advised the parties that if they had either procedural or constitutional objections, they could raise those issues "in their closing briefs, in order to preserve them for an appeal." Pet. App. 38a. After a four-day hearing, the ALJ upheld the OIG's determination that petitioner had violated Section 1156 and should be excluded from the Medicare program for two years. Pet. App. 11a-12a. The Appeals Council affirmed the ALJ's decision. *Id.* at 41a-42a.[7]

2. Petitioner then brought this action challenging his exclusion in the United States District Court for the Eastern District of Wisconsin. Petitioner claimed that the Secretary's decision was not supported by substantial evidence. C.A. App. 112-114. Petitioner also made several claims that he had not made in the administrative proceeding. Specifically, petitioner claimed, for the first time, that the Secretary's procedures violated due process because (1) the OIG improperly had the dual roles of "being a party to the administrative litigation and being

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[7] Four months prior to the Appeals Council's decision (at the conclusion of the two-year exclusion), petitioner was reinstated in the Medicare program, based on the OIG's determination that there was reasonable assurance that the problems that led to petitioner's exclusion would not recur. Pet. App. 43a-44a; 42 U.S.C. 1320c-5(b)(2).

engaged in the investigation"; (2) the OIG had "established a quota system for the production of penalties and exclusions to be obtained by the I.G.'s staff"; and (3) the Sec-retary's procedures did not permit discovery of evidence relevant to petitioner's conflict-of-interest and quota claims. C.A. App. 116, 119 (Counts III and IV of complaint); see Pet. App. 22a.

Petitioner later served requests on the Secretary seeking discovery bearing on his due process claims. Pet. App. 25a, 27a. On the Secretary's motion, the district court granted a protective order barring the discovery. *Id.* at 24a-30a. The court observed that under 42 U.S.C. 405(g)—which applies here by virtue of 42 U.S.C. 1320c-5(b)(4)—its jurisdiction was "limited to review * * * [of] the record of testimony, exhibits, and issues compiled in the administrative forum, along with the particular findings and conclusions regarding these submissions advanced by the Secretary—through the ALJ and Appeals Council—in support of his final administrative decision." Pet. App. 29a. The court rejected petitioner's argument that it would have been futile for him to raise his due process claims before the Secretary:

> (1) [A]ssuming [petitioner] is correct that the OIG would have objected to consideration of the [due process] issues raised in [petitioner's] discovery requests, the ALJ and Appeals Council would not have been precluded from ruling on their jurisdiction over such issues, or in the alternative allowing [petitioner] to compile a record; (2) [petitioner] never gave the ALJ and the Appeals Council the chance to consider the issues raised

> in his discovery requests to preserve those issues for review; (3) although [the Secretary's hearing procedures] do[] not provide for prehearing discovery, the hearing procedures do provide for production of witnesses and documents at the hearing itself, which [petitioner] availed himself of on other issues, but not those issues on which he now seeks discovery; and (4) [petitioner's] discovery requests seek more than to raise collateral or procedural issues, for they seek to compile extrarecord evidence concerning these issues.

Id. at 28a.

The court subsequently granted summary judgment for the Secretary. Pet. App. 9a-23a. The court first held that the Secretary's decision to exclude petitioner from the Medicare program was supported by substantial evidence. *Id.* at 13a-20a. With respect to patient H.D., the district court determined that the evidence was sufficient to support a finding that petitioner "failed to employ adequate diagnostic skills, thereby failing to recognize H.D.'s deteriorating condition, and * * * failed to obtain timely outside cardiac consultation." *Id.* at 14a. The court further determined that petitioner's care of H.D. deviated from professionally recognized standards of health care. *Id.* at 14a-15a. With regard to patient L.M., the district court similarly held that the evidence was sufficient to support a finding that petitioner "placed L.M. at substantial risk and in very real danger of imminent death," *id.* at 20a, by failing to seek a cardiac consultation when it became apparent that his course of treatment was ineffective and that L.M.'s

condition was deteriorating, *id.* at 15a-20a. In addition, the district court found substantial evidence to support the conclusion that petitioner "ha[d] been unwilling and unable to comply substantially with his Social Security Act obligations." *Id.* at 21a.

The district court declined to address petitioner's due process claims, observing that "[d]espite the ALJ's * * * admonition regarding preserving issues and documents for appeal, [petitioner] failed to follow these dictates." Pet. App. 22a. Relying on its earlier decision entering a protective order, the court concluded that "[a]n issue not raised in the administrative phase of this action cannot be before this Court." *Ibid.*

3. The court of appeals affirmed. Pet. App. 1a-8a. It held, first, that "there is not only substantial, but abundant evidence in the record to support the ALJ's decision that [petitioner] grossly and flagrantly violated his section 1156 obligations." *Id.* at. 5a. The court similarly held that substantial evidence supported the ALJ's determination that petitioner was unwilling and unable to comply substantially with his obligations under Section 1156. Pet. App. 6a. The court further held that the district court did not abuse its discretion in granting the Secretary's motion for a protective order. *Id.* at 7a. The court of appeals explained that petitioner's discovery requests sought evidence outside the certified record, which, under 42 U.S.C. 405(g), the district court was expressly precluded from considering. Pet. App. 7a. Finally, the court of appeals upheld the district court's refusal to consider petitioner's due process arguments, stating: "Our rule is that these issues

must first be raised administratively." *Ibid.* (citing *Weyerhaeuser Co.* v. *Marshall*, 592 F.2d 373, 376 (7th Cir. 1979)). Thus, the court of appeals "decline[d] to consider issues not considered by the Appeals Council." Pet. App. 7a.

ARGUMENT

Petitioner does not challenge the court of appeals' holding that "abundant" evidence (Pet. App. 5a) supports the Secretary's determination that he grossly and flagrantly violated his obligations under Section 1156 and was unable and unwilling substantially to comply with those obligations. Instead, petitioner argues that the courts below erred in declining to consider his due process claims. Those courts correctly concluded, however, that petitioner was not entitled to judicial review of his due process claims because he failed to raise them before the Secretary. That conclusion, moreover, does not conflict with any decision of this Court or any court of appeals. Further review is therefore not warranted.

It is well established that "where Congress has provided statutory review procedures designed to permit agency expertise to be brought to bear on particular problems, those procedures are to be exclusive." *Whitney Nat'l Bank* v. *Bank of New Orleans & Trust Co.*, 379 U.S. 411, 420 (1965). As this Court has explained, administrative exhaustion "is generally required as a matter of preventing premature interference with agency processes, so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its experience and expertise, and to compile a record

which is adequate for judicial review." *Weinberger* v. *Salfi*, 422 U.S. 749, 765 (1975).

Under the provisions governing judicial review in this case, the exhaustion requirement is "more than simply a * * * judicially developed doctrine"; it is "a statutorily specified jurisdictional prerequisite." *Salfi*, 422 U.S. at 766; accord *Heckler* v. *Ringer*, 466 U.S. 602, 619 n.12 (1984); *Doyle* v. *Secretary of Health & Human Servs.*, 848 F.2d 296, 299 (1st Cir. 1988). Specifically, 42 U.S.C. 1320c-5(b)(4) limits judicial review to review of the "Secretary's final decision * * * as is provided in [42 U.S.C.] section 405(g)." This Court has stated, in turn, that the "final decision" requirement in Section 405(g) is "central to the requisite grant of subject-matter jurisdiction," *Salfi*, 422 U.S. at 764, and

> consists of two elements * * *. The waivable element is the requirement that the administrative remedies prescribed by the Secretary be exhausted. The nonwaivable element is the requirement that a claim for benefits shall have been presented to the Secretary.

Bowen v. *City of New York*, 476 U.S. 467, 483 (1986) (quoting *Mathews* v. *Eldridge*, 424 U.S. 319, 328 (1976)).

In accordance with the exhaustion requirement in Section 405(g), "all aspects" of a claim, including constitutional challenges, must "be channeled first into the administrative process which Congress has provided." *Ringer*, 466 U.S. at 614; see also *Salfi*, 422 U.S. at 762 (under 42 U.S.C. 405(h), constitutional claims must be "brought under jurisdictional grants contained in the [Social Security] Act, and thus in

conformity with the same standards which are applicable to nonconstitutional claims arising under the Act"). Except where the Secretary has waived the requirement of full exhaustion or where a court may properly impute a waiver of that requirement, see, *e.g.*, *City of New York*, 476 U.S. at 483-486, the failure to raise a claim during the administrative process precludes courts from subsequently considering that claim.

Here, the court of appeals correctly concluded (Pet. App. 7a) that this case "falls within the rule [requiring exhaustion], not the exception," *Doyle*, 848 F.2d at 300.[8] This is not a case in which the Secretary has waived the exhaustion requirement or in which a court could properly infer a waiver. Cf. *Salfi*, 422 U.S. at 767.

First, the ALJ specifically invited petitioner to identify any constitutional issues in order to "preserve" them in the case, but he declined to do so.

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[8] Cf. *Winter* v. *California Medical Review, Inc.*, 900 F.2d 1322, 1324-1326 (9th Cir. 1990) (dismissing, on exhaustion grounds, suit by excluded physician challenging PRO's authority to review quality of his surgery); *Avol* v. *Secretary of Health & Human Servs.*, 883 F.2d 659, 661 (9th Cir. 1989) (declining to review excluded physician's contention that PRO's contract did not entitle it to conduct quality reviews because that contention was "not raised before the SSA Appeals Council"); *Hussain* v. *Secretary of Health & Human Servs.*, 748 F. Supp. 277, 279 (D.N.J. 1990) (dismissing, on exhaustion grounds, suit by physician seeking to enjoin his exclusion from Medicare program); see also *Lavapies* v. *Bowen*, 883 F.2d 465, 467-468 (6th Cir. 1989) (addressing constitutional claims by excluded physician on merits, but affirming dismissal, on exhaustion grounds, of physician's other claims, including claim that PRO was under a "quota" system).

Pet. App. 38a. As the district court observed (*id.* at 28a), petitioner "never gave the ALJ and the Appeals Council the chance to consider those issues," or to "rul[e] on their jurisdiction over such issues." Petitioner thus effectively waived those issues.

Second, petitioner's due process claims are not "wholly collateral" to his substantive challenge to the Secretary's decision. See *Ringer*, 466 U.S. at 618 (internal quotation marks omitted). Like the plaintiffs in *Ringer*, although petitioner "assert[s] objections to the Secretary's 'procedure' for reaching [his] decision," at bottom his objections are "inextricably intertwined" with his claim that he should not have been excluded from the program. *Id.* at 614. That is clear from petitioner's complaint, which requested relief aimed solely at reversing the effects of his exclusion, rather than at revamping the Secretary's decision-making procedures.[9] Cf. *City of New York*, 476 U.S. at 483 (plaintiffs challenging Secretary's secret, internal policy "neither sought nor were awarded benefits"); *Cassim* v. *Bowen*, 824 F.2d 791, 795 (9th Cir. 1987) (physician's suit seeking pre-exclusion hearing was collateral to merits of exclusion).

Furthermore, it cannot be said in this case that "there [is] nothing to be gained from permitting the

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[9] In his complaint, petitioner asked for retroactive reinstatement and payment of his Medicare claims; a declaration that his exclusion was illegal; and an injunction prohibiting the OIG from reviewing his Medicare activities or excluding him "while the PRO's are under the direction of the OIG." C.A. App. 120.

compilation of a detailed factual record, or from agency expertise." *City of New York*, 476 U.S. at 485. Petitioner's primary due process claim is that the OIG used a "quota" system for imposing exclusions and other sanctions. Pet. i, 5, 6-7, 8, 11. Yet there is no evidence in the administrative record regarding this alleged quota system. And the only evidence in the court proceedings is a heavily excerpted performance appraisal that covered a different period from the period during which petitioner's case was before the OIG. See Pet. App. 45a-46a. Nonetheless, in this Court petitioner does not dispute the district court's determination that he could have obtained evidence bearing on his due process claims under the Secretary's hearing procedures. *Id.* at 28a. Moreover, petitioner also could have presented argument on those claims, as the ALJ made clear in stating that the parties could raise "procedural/constitutional issues" in their post-hearing briefs. *Id.* at 38a. In light of petitioner's failure to avail himself of these procedures, the courts below properly declined to decide his constitutional claims "devoid of [a] factual context." *W.E.B. DuBois Clubs of America* v. *Clark*, 389 U.S. 309, 312 (1967).[10]

Petitioner nonetheless contends (Pet. 6, 8-9) that the courts below were required to consider his claims under *Bowen* v. *Michigan Academy of Family*

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[10] It should be noted that petitioner's "quota" argument is, in any event, of no continuing importance. We are informed by HHS that the portion of the performance appraisal held invalid in *Melashenko* v. *Bowen*, No. CV-F-87-533 (E.D. Cal. June 19, 1990), has been significantly revised to conform to that decision.

Physicians, 476 U.S. 667 (1986). That contention, however, is based on petitioner's erroneous assertion that *Michigan Academy* created an exception to the exhaustion requirement for all "constitutional, due process, methodology/procedural type issues" related to the Secretary's administration of the Medicare program. Pet. 6. The decision cannot be read so broadly.

Michigan Academy concerned a challenge by physicians to a regulation promulgated by the Secretary governing the amount of benefits payable under Part B of the Medicare program. 476 U.S. at 668-669. The question was whether judicial review of Part B regulations was barred by either 42 U.S.C. 1395ff(b), which at the time authorized judicial review of benefit amount determinations only under Part A, or 42 U.S.C. 1395ii, which makes 42 U.S.C. 405(h) applicable to the Medicare program. *Michigan Academy*, 476 U.S. at 673. The Court held that neither provision barred judicial review. *Id.* at 674-681. In so holding, the Court emphasized the "strong presumption that Congress intended judicial review of administrative action." *Id.* at 670; see also *id.* at 681.

Michigan Academy is inapposite in the present case. None of the statutory provisions at issue in *Michigan Academy* is applicable here. Moreover, there is no dispute that petitioner was entitled to judicial review of the Secretary's final decision excluding him from the Medicare program. See 42 U.S.C. 1320c-5(b)(4). Rather, the question is whether, in reviewing the Secretary's decision, the courts were required to consider claims that petitioner did not raise during administrative proceedings and as to

which no administrative record had been compiled.[11] As explained above, under this Court's decisions construing Section 405(g)—the provision authorizing judicial review in this case—the courts were not required to consider the claims that petitioner failed to raise in administrative proceedings.[12]

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[11] The sixth sentence of 42 U.S.C. 405(g) provides for a remand to the Secretary if there is additional evidence relevant to the district court's review of the case, rather than for the district court to receive such evidence itself (as petitioner sought here through his discovery requests). Moreover, such a remand may be ordered only if the evidence is "new" and "material" and there is "good cause" for the failure to incorporate it in the record in the administrative proceedings. See *Melkonyan* v. *Sullivan*, 111 S. Ct. 2157, 2164-2165 (1991). In light of petitioner's failure to preserve the due process issues and to introduce evidence concerning them in the administrative proceedings, he plainly has not shown "good cause" for a remand to the Secretary to develop the sort of evidentiary record that would be necessary to enable a court to consider the due process issues.

[12] This case need not be held pending this Court's disposition of *Darby* v. *Kemp*, cert. granted, 113 S. Ct. 404 (1992) (No. 91-2045). *Darby* presents the question whether, under the circumstances of that case, exhaustion of administrative remedies was required in the absence of a statute expressly requiring exhaustion. The present case, in contrast, concerns the application of a statutory exhaustion requirement: namely, 42 U.S.C. 405(g), which is made applicable to judicial review of exclusion decisions by 42 U.S.C. 1320c-5(b)(4). See generally *McCarthy* v. *Madigan*, 112 S. Ct. 1081, 1086 (1992) (distinguishing exhaustion required as a matter of "sound judicial discretion" from exhaustion "specifically mandate[d]" by Congress).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 1992

Supreme Court, U.S.
FILED
DEC 30 1992
OFFICE OF THE CLERK

No. 92-652

In The

Supreme Court of the United States

October Term, 1992

DAVID E. PAPENDICK, M.D.,

Petitioner,

vs.

LOUIS SULLIVAN, SECRETARY UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN HIS OFFICIAL CAPACITY, APPEALS COUNCIL #000-54-7038,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

REPLY BRIEF FOR PETITIONER

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APPENDIX

Appendix A — Excerpts of Federal Regulation 42 C.F.R. § 1005 ..... 1b

REPLY BRIEF

The Respondent has asserted various legal positions and factual allegations that are not consistent with the facts and law nor complete in their presentation. First, the Respondent asserted on page 5 of his brief that the "Petitioner declined to request a meeting with WIPRO". While that is technically correct, it ignores the fact that the Petitioner had not been informed that he could be represented by counsel at the meeting with WIPRO or that a corrective plan could be negotiated at such a meeting. The latter was not explained to him,probably because WIPRO did not normally negotiate such corrective plans. This refusal to extend the opportunity to undertake corrective plans as required by statute [42 U.S.C. § 1320c-5(b)] (Pet. App. 55a) was based upon financial considerations of WIPRO, as testified to by Dr. Jonathan Moulton (Pet. App. 52a), WIPRO's expert witness at Petitioner's administrative exclusion hearing.

The Respondent seeks to have this Court deny Petitioner its review based on the Respondent's erroneous assertion that "Petitioner does not challenge the court of appeals' holding that 'abundant' evidence supports the Secretary's determination that he grossly and flagrantly violated his obligations under Section 1156 and was unable and unwilling substantially to comply with those obligations." This is erroneous on two basis. First, the Petitioner *does* dispute such a finding and second, the Respondent confuses the certiorari worthiness of a particular issue in a lawsuit with the certiorari worthiness of the lawsuit, itself. The fact that Petitioner did not seek to have this Court weigh through minutia of evidence to determine if the court of appeals erred as to its weighing of evidence as to a possible gross and flagrant violation does not mean that Petitioner concedes that issue, but, rather, recognizes that such an issue is unworthy for this Court's consideration.

The fact that the Respondent reinstated Petitioner in the

departmental health care programs prior to the completion of Petitioner's administrative review (Pet. App. 41a, 43a) is substantial evidence that Petitioner was in fact able and willing to comply with his obligations for the IG was required to determine that it had reasonable assurance that a reoccurrence of the cause for exclusion would not take place, prior to reinstating Petitioner [42 C.F.R. § 1004.120(a)] (Pet. App. 59a). These simple facts demonstrate that Petitioner was and is no medical butcher but, rather, was legal fodder for the OIG's quota system.

Next, we must consider the Respondent's repeated mischaracterizations concerning the ALJ's determination that he had no jurisdiction to consider constitutional issues. On page 6 and page 14 of Respondent's brief, the Respondent asserted that the ALJ advised the parties that "they could *raise* those issues (constitutional or procedural) 'in their closing briefs, in order to preserve them for an appeal.' " (emphasis added). Furthermore, the Respondent asserts on page 14 that "in this Court petitioner does not dispute the district court's determination that he could have obtained evidence bearing on his due process claims under the Secretary's hearing procedures."

First, the ALJ did not advise the parties that they "raise" constitutional or procedural issues in the briefs but, rather, that "the parties *may* (not must) however *insert* objections on procedural/ constitutional issues in their closing briefs, in order to preserve them for appeal." (emphasis added). This was after the ALJ specifically held that he "has no jurisdiction to rule on constitutional issues." (p. 38a). This latter determination of the ALJ was not administratively appealed by the Inspector General and it must be considered a final determination of the agency. The Petitioner happened to agree and agrees with the ALJ's assertion of his limited authority. Therefore, Petitioner had nothing to appeal as to that decision. The ALJ did not invite the parties to *raise* such issues but to *insert* them. The ALJ did *not authorize* the parties *to*

litigate constitutional/procedural issues nor *to document* these issues. He did *not authorize* the parties *to subpoena witnesses* during the hearing concerning constitutional/procedural issues *nor to seek discovery*[1] as to these issues. He only extended an offer to permit the parties to "insert" the issues in their closing briefs and, at that, it was not phrased as a mandatory but permissive insertion. Indeed, he even acknowledged that he had no jurisdiction to consider such issues.

The ALJ's offer in the Petitioner's pre-hearing order was limited and reflective of his limited authority. These limitations have been codified in the Respondent's new regulations implemented January 27, 1992 (p. 61a). The ALJ did not and does not have authority to "find invalid Federal statutes or regulations or Secretarial delegations of authority;" [42 C.F.R. § 1005.4(c)(1) (Appendix at 1b, *infra*)]. Furthermore, current discovery procedures which did not even exist prior to the new regulations only provides for production of documents which are "relevant and material to the issues before the ALJ" [42 C.F.R. § 1005.7(a) (Appendix at 2b, *infra*)]. Inasmuch as the constitutionality of the secretarial delegation of authority to the OIG to exclude individuals while using a bonus/quota system is not an issue which can be raised before an ALJ, discovery does not exist even today for such an issue.

As to the ALJ's determination of his limited authority, the Inspector General did not even object thereto, let alone appeal therefrom. The Inspector General failed to exercise his administrative appeal rights and can not now assert them contrary to the procedures, then accepted by all parties.

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1. Discovery was non-existent under the prior hearing regulations and, as will be seen, discovery as to the subject issue in this matter is not available under current regulations.

Next, we must address the Respondent's assertion on page 10 that the courts correctly concluded that "Petitioner was not entitled to judicial review of his due process claims because he failed to raise them before the Secretary" and that such "conclusion, moreover, does not conflict with any decision of this Court or any court of appeals." First, such a conclusion does conflict with this Court's prior decision in *Bowen v. Michigan Academy of Family Physicians,* 106 S. Ct. 2133, 2140-2142 (1986). The fact is that this review is not predicated upon 42 U.S.C. § 405(g) jurisdiction but, rather, general federal question jurisdiction (28 U.S.C. § 1331) as under *Michigan Academy, supra.* This issue will be addressed in depth later herein.

Assuming, however, for argument sake that appeal in this matter is based upon 42 U.S.C. § 405(g) jurisdiction, the issue appealed herein is not barred by that sections exhaustion requirements. Decisions of various courts of appeal, where the exhaustion of administrative remedies was waived, are in conflict with the holding below and exhaustion should have been waived below; *see Ellison v. Califano,* 546 F.2d 1162, 1164 (5th Cir. 1977) held waiver of administrative exhaustion was appropriate when exhaustion would have been futile; *also see, Koerpel v. Heckler,* 797 F.2d 858, 866 (10th Cir. 1986); *Gipson v. Harris,* 633 F.2d 120, 122 (8th Cir. 1980); *Singer v. Schweiker,* 694 F.2d 616, 618 (9th Cir.1982); in *Klein v. Sullivan,* 978 F.2d 520, 524 (9th Cir. 1992) the court found that the administrative agency was unsuited to resolve colorable constitutional collateral challenges while finding that the matter should be moved "immediately to the district court for prompt resolution".

Aside from the waivability of the exhaustion of administrative remedies as discussed above, it is Petitioner's position that there were no administrative remedies to exhaust and under *Michigan Academy, supra,* Petitioner was and is entitled to bring an action under the general federal question jurisdiction of the district court

as defined by 28 U.S.C. § 1331. The Respondent, on page 11, relies upon *Heckler v. Ringer,* 466 U.S. 602, 614 (1984) and *Weinberger v. Salfi,* 422 U.S. 749, 762 (1975), to assert that review of Petitioner's due process claim is inappropriate. The cases of this Court cited by Respondent predate the Court's holding in *Michigan Academy, supra,* and the Respondent ignores the lessons learned from *Michigan Academy, supra.*

The fact is that when the Respondent, to whom Congress has delegated primary authority to implement the Social Security Act, fails to establish administrative appeal procedures in which to channel various constitutional issues, then these issues need not be brought on, under the Act, in order to obtain judicial review. It is as to such issues that the Social Security Act does not restrict judicial review to § 405(g) jurisdiction. For when Respondent provides no avenues for administrative review as to constitutional issues, then Respondent has relinquished any right or justification to assert the prerequisite of § 405(g) exhaustion prior to submitting Respondent's implementation of the Act to judicial review. To restrict judicial review of constitutional issues, when the Act as implemented by Respondent provides for no administrative appeal, would "raise a serious constitutional question of the validity of the statute as so construed", *Salfi, supra,* 762. If the Respondent established procedures to provide for a meaningful administrative appeal, then it could be argued that even constitutional issues should be first channeled through those procedures; however, without such procedures in which to channel such administrative appeals, the constitutional issues need not be and cannot be first presented to the agency under § 405(g) jurisdiction, but, rather, general federal question jurisdiction of the district courts is to be presumed available.

This Court addressed methodology issues in *Michigan Academy, supra,* 2138-2142, and distinguished them from amount determinations. The amount determination of a financial claim

case could be said to be the equivalent to an outcome determination when considering whether or not to exclude a provider from Medicare participation and for what period of time. This type of determination is in contrast to a determination as to the validity of the method of how a provider is to be excluded. In general, the Secretary has not provided for administrative appeals pertaining to challenging the methodology procedures used in determining how a provider is to be excluded; but, rather, only, within certain limits[2], as to the outcome of whether a provider is to be excluded and if so, for what period of time.

In the present case, the bonus/quota system of the OIG is not an issue which is subject to the administrative appeal process and cannot be considered to have an administrative appeal procedure available through which the constitutionality of the issue could be channeled. Furthermore, the methodology of the Respondent's determination process is what is being challenged and not the amount (or outcome). Because of the foregoing, it would not be appropriate to restrict Petitioner's appeal to 42 U.S.C. § 405(g) jurisdictional grounds.

In the present case, an individualized application of a specific regulation is not in issue. The structure or methodology of the administrative exclusion process itself is in issue. What must be

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2. Under current regulations, the ALJ's authority is restricted to determining if a violation of certain discretionary exclusionary provisions under the Act has occurred. If such a violation has occurred, then the ALJ is precluded from reviewing the OIG's exercise of discretion in determining to exclude a provider [*see* 42 C.F.R. § 1005.4(c)(5) (Appendix at 1b, *infra*) and § 1005.4(c)(7) (Appendix at 1b, *infra*)]. Thus, there is no administrative review to determine if the OIG has abused the exercise of his discretion, exercised his discretion on the basis of illegal criteria or has otherwise violated due process in the exercise of his discretion to exclude a provider. This absolute, non-reviewable discretion sought by the OIG is more in accordance with the procedures of a police state than a democracy.

addressed is the constitutionality of the Respondent's delegation of authority to the Inspector General wherein the Inspector General is applying such a bonus/quota system.[3] Petitioner was entitled to a *fair* and *impartial initial decisionmaker* and this is what *he was denied.* The administrative appeal procedures *does not* and *cannot* address this issue. Therefore, the issue cannot be said to be restricted to being addressed through 42 U.S.C. § 405(g) jurisdiction. The issue is of a constitutional dimension and Congress must be presumed to have expected that it would have a judicial forum in which to be heard, *Michigan Academy, supra,* 2140-2142, and *Salfi, supra,* 762. Respondent cannot be permitted to deprive Petitioner and others similarly situated of judicial review of constitutional issues by precluding administrative review procedures. This issue cannot be resolved merely by an ALJ applying a regulation to come to a different amount (outcome) determination because it cannot to be resolved by merely altering the application of a regulation. It involves a structural defect in the Respondent's administrative procedures and an ALJ has no more authority to correct it (p. 61a), than the Respondent Secretary has to correct an unconstitutional act of Congress.

The issue herein addresses the structure of the administrative exclusion process and it is not "inextricably intertwined" with an amount (outcome) determination as argued by the Respondent on page 13. On page 13, the Respondent misstates a factor which Respondent alleges to be pertinent for this Court's consideration. Thereat, the Respondent asserted that the Petitioner sought relief that was "solely aimed at reversing the effects of his exclusion, rather than revamping the Secretary's decision-making

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3. The Respondent has not challenged in this litigation the characterization, of the Performance Appraisal System of the OIG official exercising exclusion authority, as being a quota/bonus system.

procedures."[4] In reality, Petitioner sought injunctive relief against the Respondent which would structurally alter the Respondent's exclusion process. Petitioner's prayer to the district court in his complaint included relief "enjoining the Defendant not to cause or permit any further PRO review of or exclusion against Plaintiff while the PRO's are under the direction and supervision of the OIG." This would certainly result in a revamping of the Respondent's administrative procedures if Respondent honored the court's determination. If the Respondent were to ignore the court's determination, then nothing could constitute relief resulting in the revamping of the Secretary's decision-making procedures.

The following factors should be considered in determining that the quota/bonus system issue addressed herein should be litigated under general federal question jurisdiction instead of

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4. Petitioner does not concede that if this were the case, as alleged by the Respondent, that the relief Petitioner sought somehow relegated Petitioner's claim to a status less entitled to consideration under general federal question jurisdiction. Otherwise, only class action type cases would be entitled to consideration as methodology type cases. If Petitioner was not concerned about revamping the Respondent's structure but only in obtaining the relief for himself, other claimants similarly situated would still be entitled to apply under Fed. R. Civ. Proc. 71 for enforcement of similar injunctive benefits as Petitioner. As for Petitioner's issue being "inextricably intertwined" with an amount (outcome) determination, Respondent can always assert that methodology relief will effect the outcome of administrative litigation because procedural safeguards often effect the outcome of administrative processes. That is why they exist. Therefore, merely because the outcome of an administrative process may be effected by the resolution of a constitutional issue, it does not mean that such result makes the issue an amount (or outcome) issue versus a methodology issue. Indeed, the Respondent could, often in administrative matters involving contested methodology issues, correct the constitutionally defective procedure and re-initiate his review under a constitutionally correct methodology, if the corrected procedure showed that the situation warranted such an effort.

§ 405(g) jurisdiction. The issue, which is being addressed, is of a constitutional dimension. Respondent did not (and does not) provide for a direct administrative appeal process to address the issue in question. The issue pertains to the methodology of how the Respondent's decision-making process functions and not a specific, limited application of a regulation.[5] Because the Respondent does not provide for administrative appeal of issues such as the subject delegation of authority issue raised herein, because it is of a constitutional dimension and because it pertains to the methodology of how the Respondent's decision-making process functions, it is clear that general federal question jurisdiction can be and ought to be applied in this matter.[6]

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5. However, an unconstitutional regulation, which directly relates to how a decision is made, without meaningful administrative appeal procedures, can also constitute an issue for general federal question jurisdiction.

6. Not all factors have to be answered affirmatively to result in general federal question jurisdiction. In this matter, all such factors indicate the appropriateness of such jurisdiction.

CONCLUSION

Based upon the foregoing, Petitioner ought to be granted a writ of certiorari for the review of the constitutionality of his exclusion wherein the OIG used a bonus/quota system in its initial exclusion determination of Petitioner. Whether this judicial review is based upon 42 U.S.C. § 405(g) jurisdiction or general federal question jurisdiction (28 U.S.C. § 1331), this fundamental issue of fairness should be considered by this Court.

Respectfully submitted,

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Dated: December 30, 1992

APPENDIX A — EXCERPTS OF FEDERAL REGULATION 42 C.F.R. § 1005

42 C.F.R. § 1005.4(c)(1)

> (c) The ALJ does not have the authority to—
>
> (1) Find invalid Federal statutes or regulations or Secretarial delegations of authority;
>
> * * *

42 C.F.R. § 1005.4(c)(5)

> (5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act, or determine the scope or effect of the exclusion.
>
> * * *

42 C.F.R. § 1005.4(c)(7)

> (7) Review the exercise of discretion by the OIG to impose a CMP, assessment or exclusion under part 1003 of this chapter.

Appendix A

42 C.F.R. § 1005.7(a)

§ 1005.7 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ.

* * *